

Data Exclusivity for Biologics

An Emerging Multilateral Standard?

A thesis submitted in fulfilment of the
requirements for the Degree of Master of Laws
in the University of Canterbury
by Máté Hegedus-Gaspar
University of Canterbury
2020

Abstract

Biological medicines, or biologics, revolutionised the treatment of some of the most serious medical conditions. These are highly research-intensive pharmaceuticals and their development requires enormous expenditure. Countries with strong innovative pharmaceutical industry have been promoting the protection of undisclosed safety and efficacy data relating to biologics by including data protection provisions in regional and bilateral trade agreements. This is a controversial endeavour that not only has been criticised by commentators, but has also led to serious complications in trade negotiations.

Many countries regulate the protection of clinical data relating to biologics, but it has never been subject to multilateral negotiations. Consequently, while data protection provisions are being routinely included in trade agreements, there is no international consensus on the standard.

This thesis analyses the phenomenon of an emergent IP protection standard, namely data protection for biologics, and its relationship to the multilateral framework. It explores various aspects and consequences of the paucity of an accepted multilateral standard. Throughout the analysis, it draws attention to the mismatch between the underlying IP principles and the prevalent methods of implementation.

The thesis proposes a hypothetical multilateral standard by bringing together all theoretical and practical aspects of the analysis, and, finally, demonstrates the utility and practical consequences of the proposed norm.

Acknowledgments

This thesis work is a continuation of a previous research paper I wrote as an undergraduate. The publication of that paper in the Journal of World Trade was the highlight of my legal career, for which I owe my deepest gratitude to the person who guided and supported me throughout my endeavour and who agreed to be my supervisor once again. This work, just like my previous research paper, would not have been possible without the help of my supervisor, Dr Christian Riffel.

I would also like to express my appreciation to Emma for her invaluable contribution, which came at a time when I needed it the most.

Finally, my deepest gratitude goes to my family, especially to Vera for her unwavering support and patience, and for believing in me so strongly. Izabella, Benjamin, Eva, Samuel and little strawberry, you often had to go to bed before I got home. Thank you for being patient with me.

Contents

I. Introduction	5
II. Regulatory Data Protection.....	11
A. Clinical data as a public good or the justification for data exclusivity in biologics.....	13
B. The regulatory nature of data exclusivity	16
C. The origins of data protection	18
D. The role of data protection	20
III. A multilateral standard of data protection for biologics?	28
A. Emerging standards	28
B. Approaching multilateralisation through megaregulation	30
C. Data protection in WIPO	31
D. Article 39.3 TRIPS.....	33
E. Data protection in FTAs.....	39
F. Choice of fora	63
G. Theory, rationale and legal principles behind data protection	67
H. The practical reality of negotiations.....	71
I. Synthesis of a multilateral standard for the protection of clinical data relating to biologics	73
J. The utility of a multilateral standard	77
IV. Potential conflicts arising from the proposed multilateral standard	79
V. Conclusions	81
Bibliography	82

I. Introduction

After many years and many rounds of negotiations the Trans-Pacific Partnership (TPP), often described as the world's largest free trade agreement in terms of GDP,¹ was finalised in late 2015 and signed by the negotiating parties in 2016. Amongst the most controversial and heavily debated provisions were those relating to data protection for biological pharmaceuticals (biologics). Biologics are pharmaceutical drugs derived from, or produced via, living organisms by using biotechnological methods. Significant compromise was required on the part of the US before an agreement was reached on the issue.

Despite the executive decision to sign, the US Congress did not ratify the agreement, and the US eventually withdrew from the deal in early 2017.² The remaining eleven countries (the TPP-11) resumed negotiations, swiftly suspended the most controversial provisions, renamed the agreement to Comprehensive and Progressive Trans-Pacific Partnership Agreement and signed in 2018.³ Amongst the suspended provisions were the above-mentioned sections relating to pharmaceutical data protection.

The suspended provisions clearly indicate what the major sticking points were that caused much of the delay in reaching the original agreement in 2016. Due to the secretive nature of the negotiations there is limited information available, but it seems clear that the majority of the remaining countries were opposing the US on the above points, hence the revision and the consequential agreement came to pass quickly. Indeed, early on in the negotiations New Zealand expressed serious concerns about the proposed intellectual property (IP) chapter and the risks of going beyond the standards agreed to in TRIPS.⁴ However, the fact that the unpopular provisions were only suspended and not removed indicates that the TPP-11 are open to the possibility that the US may be re-entering the deal at a future date with a similar agenda. Recent developments, however, cast serious doubt as to the US intentions in this regard.

While the TPP countries came very close to yielding to the US Trade Representative's relentless push to introduce a higher level of market protection for biologics, a similar set of provisions were also part of an agreement-in-principle, the now-amended United States-Mexico-Canada Agreement (USMCA) signed in 2018.⁵

The 2018 version of the USMCA contained a data protection regime developed along the same lines as was initially proposed by the US during the TPP negotiations. However, the White House, at the insistence of the Democratic majority of the House of Representatives, agreed to remove the biologics

¹ Ministry of Foreign Affairs and Trade, *TPP Overview Fact Sheet* (New Zealand-specific fact sheets on the content of TPP, 2015) 3.

² Donald J. Trump, 'Presidential Memorandum Regarding Withdrawal of the United States from the Trans-Pacific Partnership Negotiations and Agreement' (*Whitehouse Official Website*, 23 January 2017) <<https://www.whitehouse.gov/presidential-actions/presidential-memorandum-regarding-withdrawal-united-states-trans-pacific-partnership-negotiations-agreement/>> accessed 16 July 2020.

³ United States Federal Food, Drug, and Cosmetic Act of 1938, Pub L No 75-717, 52 Stat 1040 (CPTPP).

⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994), Marrakesh Agreement Establishing the World Trade Organization (1994), Annex 1C, 1869 UNTS 299 (TRIPS); *New Zealand TPP Intellectual Property Chapter: Horizontal Issues/Overall Structure, General Provisions and Cooperation* (Leaked Document, 2010) 1.

⁵ Biotechnology Innovation Organization (BIO), *A Follow-On Biologics Regime Without Strong Data Exclusivity Will Stifle The Development Of New Medicines* (White paper, 2007) (USMCA).

data protection provision from the final version of the USMCA.⁶ Therefore, as it stands today, both attempts at raising the level of data protection for biologics failed.⁷ Although, the amendment of the USMCA would better be framed as a reconsideration, initiated by the US body politic, a result of a democratic process, rather than a failure of negotiations.

In contrast, the EU and Canada successfully concluded the Comprehensive Economic and Trade Agreement (CETA), which contained an unprecedented eight years of data protection for pharmaceuticals, including biologics.⁸ Admittedly, this part of the agreement did not require changes to domestic law in the EU, nor in Canada, but it did lock in the current level of protection, making it very difficult for either party to reduce it later.⁹

These events show that data protection for biologics is a controversial area of international trade law. This is partly due to the fact that IP protections for pharmaceuticals, in general, lend themselves to be hijacked for political purposes. Furthermore, as far as data protection *for biologics* is concerned, there is a lack of consensus as to its legal standing and proper formulation. This hiatus is partly responsible for the turbulent negotiating history of the TPP and the extraordinary double take in the conclusion of the USMCA. It is submitted in this paper that data protection for biologics is a unique IP right (IPR) by virtue of the fact that it has been developing in different locations in various formulations that seem to be slowly converging and making appearances at the international level with increasing frequency.

The failure of the USMCA and TPP biologics data protection provisions plainly illustrate the difficulty faced even by the US, previously one of the most powerful proponents of these provisions, in its attempts at working out its trade policy on the matter and the proper legal implementation of that policy. This area of law (certainly, as far as the US is concerned) is in a state of flux, and the situation is unlikely to be resolved in the immediate future.

This stands in stark contrast with the situation in regard to data protection for chemical entities. In the pre-TRIPS era the EU, closely followed by the US, introduced domestic regulations for the protection of clinical data. The US then successfully negotiated the inclusion of a data protection provision for chemical drugs in NAFTA, which is a step up in the hierarchy of laws, insofar as domestic law is subordinate to trade agreements.¹⁰ This was later taken another step higher in the hierarchy, when the TRIPS Agreement came into force. The result of this “bottom up” progression of regulation is a legal structure where the mandate to protect clinical data now originates in the TRIPS agreement, arguably at the pinnacle of laws. In this sense, the resulting legal structure can now be conceptualised as “top down” where the legal authority for data protection flows from the top (i.e. the TRIPS), down to trade agreements, where it is clarified, modified and usually strengthened, and, either directly from TRIPS or via an intermediary step of a trade agreement, further down to domestic law.

⁶ Protocol of Amendment to the United States-Mexico-Canada Agreement (30 November 2018, adopted 10 December 2019) (USMCA Amendment Protocol).

⁷ However, TPP art 18.50 (the data protection provision for biologics) has only been suspended, not deleted.

⁸ Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [2017] OJ L11/23(CETA); CETA art 20.29(2)(b) in conjunction with art 20.6.

⁹ Lasia Tang, 'Data protection provisions in CETA' (*Generics and Biosimilars Initiative*, 2014) <<http://www.gabionline.net/Generics/Research/Data-protection-provisions-in-CETA>> accessed 08 July 2020.

¹⁰ General Agreement on Tariffs and Trade (15 April 1994), Marrakesh Agreement Establishing the World Trade Organization (1994), Annex 1A, 1867 UNTS 187(NAFTA).

One of the consequences of the “top down” force, underlining the difference between data protection for chemical and biological drugs, was that WTO Members became obligated to introduce a minimum level of data protection for chemicals where such regulation had not existed before.¹¹

By contrast, in case of biologics, the above “top down” mandate does not exist. The development of data protection regulation is still in the “bottom up” phase insofar as countries with strong research-based pharma industry provide for data protection in their domestic law. Since no top-level mandate exists for the protection of clinical data for biologics, proponents of data protection resort to the propagation of these regulations into trade agreements in an attempt to export the protections to their trade partners.

However, there is a fundamental difference between the evolution of data protection regulation for chemical drugs and biologics. The former was adopted in WTO law at a relatively early stage, when such provisions were typically not part of trade agreements – NAFTA being the only example. Whereas the latter has already become widespread without having been adopted in WTO law, if it ever will. It is only after the coming into force of the TRIPS when data protection started to become part of bilateral and regional trade agreements. Article 39.3 of TRIPS provides a basis and context for these provisions both at the international and domestic levels. In my view, this significantly helped to keep the evolution of these regulations within certain bounds.

In case of biologics, the regulation has so far evolved largely in parallel with chemical drugs, however, in my view, this is not a necessity. In fact, the US made at least two significant, if unsuccessful, attempts to separate the two in and impose higher protection standards for biologics on its trading partners.

The purpose of this paper is to analyse the phenomenon of an emergent IP protection standard, namely data protection for biologics, and its relationship to the multilateral framework, and to explore various aspects and consequences of the paucity of an accepted multilateral standard. As previously argued, the only multilateral standard relating to pharmaceutical data protection, established under Art 39.3 of TRIPS, does not apply to biologics.¹² Consequently, there is no current, legally binding standard that would inform arguments around data protection provisions in new FTAs that specifically apply to biologics.

An internationally agreed standard would be particularly useful in light of the US approach to formulating data protection provisions, which entails separate headings for chemical drugs and biologics with different levels of protection.¹³ During the most recent negotiations, such as the USMCA and TPP, the US proposed to first lay down their well-established standard of data protection in relation to chemical pharmaceuticals, then add a section for biologics, modifying the preceding standard by adding extra layers or higher standards of protection. This is in contrast with, for example, the EU approach, where pharmaceuticals are not divided by their physical or chemical characteristics or method of manufacture.

Dealing with biologics separately, with the intention of applying a different standard of protection strongly implies that negotiators agree with the proposition that whatever the multilateral minimum

¹¹ Marrakesh Agreement Establishing the World Trade Organization (15 April 1994) 1867 UNTS 154 (WTO Agreement).

¹² M. Hegedus-Gaspar, 'Data Exclusivity for Biological Pharmaceuticals: Is New Zealand in Breach of World Trade Organization Law?' (2016) 50 Journal of World Trade 909 916-18.

¹³ Although the US's move to roll back the USMCA data protection provisions seems to indicate a move away from this approach.

level of protection for biologics might be, it is not the same as that for chemicals. This in turn begs the question: what is the multilateral minimum/maximum standard? Is a new FTA establishing a high standard, such as the minimum ten-year exclusivity originally proposed under the USMCA, in conflict with WTO law for creating a barrier to trade?¹⁴ Has this approach been abandoned because of the difficulty of justifying the different level of protection? Given that TRIPS imposes an obligation on WTO Members, including developing countries, to provide patent protection for pharmaceuticals, should one look for the answers in the perceived role of data protection regulation?¹⁵

Data protection provisions under FTAs negotiated by the US and EU have been the subject of much analysis, many articles and criticism which could fill volumes, most of which compared the requirements under the FTAs and those under TRIPS.¹⁶ Article 39.3 of TRIPS itself has been the subject of a vast literature, interpreting and analysing the meaning of each term and the provision as a whole. In contrast, data protection for biologics has no directly comparable standard at the multilateral level. Supporters and critics put forward their arguments in a relative legal vacuum. This creates an uncertain environment for negotiations, for, without an anchor point, such as Art 39.3 for chemical drugs, there is nowhere to start or converge to, during the talks.

As leading scholars have opined before, TRIPS provides clarification for WTO Members as to their obligations and their policy space with regards to IP protection.¹⁷ Importantly, it has been argued that TRIPS established minimum as well as maximum standards of protection, although in light of the second sentence of Article 1.1 thereof it remains to be seen what, if any, might be the legal consequences should a Member introduce IP protection standards that are deemed too high.¹⁸ Typically negotiators of developing countries trade IP protection provisions, for example, market access in FTA negotiations;¹⁹ however, there is significant difficulty in determining what value to place on a certain level of protection, particularly if there is no accepted basis to compare it to.

As much as TRIPS has been in the centre of criticism for all its perceived and real shortcomings, it does provide a multilaterally accepted framework with a certain amount of flexibility and policy space for implementation.²⁰ Art 39.3 of TRIPS obligates WTO Members to protect clinical data relating to chemical drugs against “unfair commercial use” in marketing approval procedures. The agreement

¹⁴ For example, General Agreement on Tariffs and Trade (15 April 1994), Marrakesh Agreement Establishing the World Trade Organization (1994), Annex 1A, 1867 UNTS 187 (GATT) art XI.1.

¹⁵ TRIPS art 27.

¹⁶ See, for example, Carlos M. Correa, 'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements' in Pedro Roffe, Geoff Tansey and David Vivas-Eugui (eds), *Negotiating Health Intellectual Property and Access to Medicines* (Routledge 2012); Susan K Sell, 'TRIPS-plus free trade agreements and access to medicines' (2007) 28 *Liverpool law review* 41; Henning Grosse Ruse-Khan, 'Protecting Intellectual Property under BITs, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?' (2011) *Evolution in investment treaty law and arbitration* 485; Henning Grosse Ruse-Khan and others, 'Principles for intellectual property provisions in bilateral and regional agreements' (2013) 44 *IIC-International Review of Intellectual Property and Competition Law* 878.

¹⁷ Grosse Ruse-Khan and others, 'Principles for intellectual property provisions in bilateral and regional agreements' 880.

¹⁸ See generally Henning Grosse Ruse-Khan and Annette Kur, 'Enough is Enough - The Notion of Binding Ceilings in International Intellectual Property Protection' (8 December 2008) Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No 09-01 1.

¹⁹ Grosse Ruse-Khan and others, 'Principles for intellectual property provisions in bilateral and regional agreements' 879.

²⁰ See, for example, TRIPS arts 7 and 8.

informs legal arguments, trade-negotiations and guides implementation. It helps create a more or less predictable environment both domestically and on the international level.

All this is missing in relation to biologics. The patchwork of FTAs that regulate data protection for biologics does not follow a single, logical and principled construction. Inasmuch as a mutual agreement on the standards laid down in TRIPS establishes a legal basis, data protection for chemicals, arguably even in the more extreme forms, such as data exclusivity or market exclusivity, has a proper international legal basis. This is not the case for biologics.

Most data protection provisions in FTAs, as will be discussed later, follow a two-part structure that, first, establishes the legal basis for data protection either by referring to Art 39.3 of TRIPS or by restating the provision; and second, describes a particular way of implementation, usually in the form of an exclusive right. The majority of FTA data protection provisions use terms that include biologics, requiring the contracting parties to grant protection to them. In my view, given that the TRIPS provision does not include biologics in its purview, it is unsound to use Art 39.3 TRIPS as a basis of data protection for this subset of pharmaceuticals. Given the high value of, and costs potentially incurred by, exclusive rights, it is reasonable to expect a proper legitimate basis thereof. Therefore, I submit that the missing link between the TRIPS Agreement and data exclusivity for biologics, is an anomaly that should be addressed.

An exclusive right to certain clinical data indirectly raises barriers to trade in otherwise legitimate follow-on products while marketing exclusivity does this directly. Considering the uncompromising nature of an exclusive right, I submit that biologics should have an internationally accepted standard that describes the right.

The lack of a multilateral agreement on this issue is particularly concerning considering that, according to one estimate, the global biologics market was worth around \$209 billion in 2017 and is growing steadily.²¹ This amounted to about 20% of the value of the entire pharmaceutical market,²² an enormous amount given that the number of biologics currently on the market is only a fraction of the number of all of the pharmaceuticals.²³ Therefore, trade in biologics has a significant overall economic impact.

The most commonly accepted reason for the research-based industry to promote longer, more comprehensive and reliable protection for biologic drugs is the high-risk nature of the investment. According to industry representatives, the development of biologics is highly research-intensive, the failure rate is disproportionately higher than in case of traditional chemical drugs and thus represents a high-cost, high-risk, long term investment.

The cost of financing such endeavours has always been high. However, legislative changes introducing abbreviated regulatory pathways in the US and EU, together with the “patent protection gap”, have

²¹ VC NewsNetwork, 'Global Biologics and Biosimilars Market 2019 Overview, Size, Share, Trend, Insights, Research, Review, Regional Analysis, Forecast Growth Report 2025' (*Reuters*, 2019) <<https://www.reuters.com/brandfeatures/venture-capital/article?id=77743>> accessed 8 May 2019.

²² See IQVIA Institute, 'Global pharma spending will hit \$1.5 trillion in 2023' (*Pharmaceutical Commerce*, 2019) <<https://pharmaceuticalcommerce.com/business-and-finance/global-pharma-spending-will-hit-1-5-trillion-in-2023-says-iqvia/>> accessed 08 May 2019.

²³ Ralf Otto, Alberto Santagostino and Ulf Schrader, 'Rapid growth in biopharma: Challenges and opportunities' McKinsey Co <<http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/rapid-growth-in-biopharma>> accessed 07 May 2019.

created additional pressure in the form of follow-on competition, pushing back on the projected return on investment. “Patent protection gap” is a term used to describe a range of complications in patenting biological substances, mainly due to their complexity and resulting difficulty of formulating an appropriate description for patenting purposes.²⁴ According to proponents of data protection for biologics, additional safeguards, such as data exclusivity or market exclusivity, are necessary to attract venture capital to fund these long-term projects.²⁵

However, opponents of such long periods of data exclusivity or market exclusivity periods point out the lack of evidence for profit losses due to biosimilar competition and the perils of undermining the patent procedure.²⁶ It has been argued that due to the relationship between original biologic and its biosimilar competitor, the latter, not being an exact replica of the former, cannot directly replace it, therefore, the chemical drug versus generic model is not applicable.²⁷

In any case, the number of countries introducing, or being required to introduce, data protection for biologics is on the rise. With world leading economies, such as the US and EU, turning to bilateral and regional agreements, data protection provisions that apply to biologics are being gradually rolled out on the international legal landscape. However, there are significant differences in the text of the different agreements, and the different standards have no common basis. A mutually accepted standard has not been explicitly agreed upon. Yet one may be emerging from the array of bilateral and regional agreements.

In this paper, I will examine the origins and evolution of data protection for biologics on the domestic level and its inclusion in international agreements. I will then turn to the question of a multilateral standard for data protection focusing on biologics. I will discuss the relationship between the existing provisions and the relevant international frameworks. Following that, I will take a look at negotiation practices and stakeholder interests that influence the development of a mutually accepted standard. In the last part I will explore some of the consequences of the paucity of an accepted multilateral standard and discuss the desirability of an international standard.

I submit that data protection for pharmaceuticals (a term that is used to include both biological and chemical drugs) is not a well-defined and homogenous type of IPR, but, on the international level, it must be treated as consisting of at least two separate parts. One part is data protection for chemical drugs which is a multilaterally accepted IPR established under Art 39.3 of TRIPS. The other part is data protection for biologics, which has not been conclusively accepted as an IPR by the international community.

I will further argue that there is an inconsistency between the standard established by TRIPS and the standards laid down in many FTAs, particularly with regards to the dual nature of data protection, i.e. whether it should be regarded as a form of IP or a regulatory regime. In other words, TRIPS establishes IP in certain clinical data and mandates its protection without specifying the nature of enforcement measures. However, data protection provisions in many FTAs establish exclusivity regimes, conflating

²⁴ Biotechnology Innovation Organization (BIO), 'The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics' (*White Paper*, 2013) 4 <https://www.bio.org/sites/default/files/legacy/bioorg/docs/files/TPP%20White%20Paper%20_2_.pdf> accessed 08 July 2020.

²⁵ Ibid 12.

²⁶ Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Completion* (Report, 2009) vi.

²⁷ Ibid.

an IPR with its enforcement measure, which clouds the definition of data protection. This phenomenon is particularly troublesome in relation to biologics.

I will conclude that it is highly desirable to have an internationally accepted standard for data protection for biologics. For this group of pharmaceuticals data protection plays a different role as compared to chemicals and it should be properly formulated, rather than left to evolve in an environment, such as bilateral and regional negotiations, where various industry groups are able to exert a disproportionately powerful force to shape the outcome.

A common standard would create a more predictable legal environment. Arguably, a properly defined and widely accepted data protection regime may provide a better, more reliable protection than patents for biologics. Ideally, such a standard is created with due consideration given to the possibility that biologic entities may not be patentable, or even if they are, the patents do not necessarily afford the same level of protection as in the case of chemical drugs.²⁸ Further, there are different ways to enforce protection, such as a direct marketing exclusivity regime, which enables open access to the protected clinical data, which may facilitate innovation better than data exclusivity regimes which restrict access to valuable information.

II. Regulatory Data Protection

In this part, I will prepare the grounds for the main argument of this paper. I will discuss those characteristics of biologics that give rise to their special position in the regulatory space. After laying out the definitions, I will move onto why and how clinical data enjoys legal protection currently. With particular attention to the difference between biologic and chemical drugs, I will discuss the interaction between the underlying IP principles and the actual regulatory protections afforded to clinical data in the existing domestic models. I will conclude that difference between data protection for biologics and chemical drugs is most important in terms of the role this IPR plays in each case in barring follow-on competition.

At the start, it is helpful to define “biologics” and to distinguish them from chemical pharmaceuticals. Further, I will briefly lay out the concept of biosimilar and generic drugs.

The legal definition of biologics or biological products varies in different jurisdiction. The US uses the following definition:²⁹

The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

In this formulation the focus is on the products themselves. The definition lists examples of biological products rather than attempting to shed light on the overarching features of the listed items. The most prominent common attribute of these products is their method of manufacture, which is based

²⁸ Deloitte, 'Avoiding no man's land: potential unintended consequences of follow-on biologics' (*White Paper*, 2009) 12 <http://www.pharmamanufacturing.com/Media/1001/Deloitte_Biosimilars.pdf> accessed 10 April 2019.

²⁹ Public Health Service Act § 351(i), 42 U.S.C. § 262(i).

on biotechnology rather than chemical synthesis. This is reinforced by the exclusion of small proteins (polypeptides) that may be manufactured by chemical synthesis. In contrast, the EU defines biological medicinal products as follows:³⁰

A biological medicinal product is a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control.

In this definition, the focus is on the manufacturing process and the need for specific testing procedures for the proper characterisation of the products. Although the two definitions seem to approach the subject from rather different angles, in practice, both definitions capture the products that are regarded as biological products by the industry.

The terms most commonly used in FTAs in the context of data protection are “pharmaceutical products” or simply “pharmaceuticals”. Given that Art. 39.3 of TRIPS refers to “pharmaceuticals [...] which utilize new chemical entities”, it may be observed that pharmaceuticals are recognised as a collective term. This aligns with common usage, where it includes any compound made for medicinal use.³¹ Therefore, it seems uncontroversial that pharmaceuticals include biological products.

Chemical drugs, also called small-molecule drugs, are manufactured using physical and chemical procedures. The end-products of these traditional chemical syntheses can be accurately characterised and described, for example, for patenting purposes. The manufacturing process can be repeated or recreated by competing manufacturer with relative ease. The traditional chemical pharmaceutical industry has developed and matured since the early 19th century.³²

Biologics, by contrast, are large molecules compared to chemical drugs, made via a living system using biological processes, for example, cell-cultures or, historically, animals. On a fundamental level, every molecule, regardless of its origin, is made of atoms, connected to each other in a primary structure. This primary structure is often sufficient to describe and identify small molecules. However, this does not apply to biologics.

Apart from the thousand-fold difference in molecular mass, biologics have a vastly more complex three-dimensional structure. While it is possible to describe the primary structure of a biologic molecule, it is an insufficient characterisation of the moiety as an active substance, because the way it is folded in space is inseparable from its function. It is extremely difficult, if not impossible, to make an exact copy of a particular biologic medicine without having access to the original biological system. This is partly due to the fact that the biotechnology industry that produces biologic medicines is relatively young, and the underlying science is not as well explored and understood as in the case of the traditional chemical industry.

Developing an original medicine takes many years of intensive research and development, which requires a large, high-risk investment. Naturally, there are participants in the pharmaceutical market

³⁰ Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67, Art 3.2.1.1(b).

³¹ 'pharmaceutical', *Oxford dictionary of English* (3rd edn, 2010).

³² Deloitte, 'Avoiding no man's land: potential unintended consequences of follow-on biologics' 3.

that specialise in creating copies, or “follow-on” products, of original medicines that have an established market.

Due to the differences in the nature of chemical and biological medicines, as explained above, follow-on competition is different in each case. In the traditional chemical pharmaceutical industry follow-on products are called generics, whereas in the biotechnology industry the term for follow-on products has now been widely accepted as biosimilars, rather than the initially floated biogenerics. In the traditional pharmaceutical industry, the term “generic” is synonymous with “identical copy”. Consequently, it would have been misleading to use the same term in relation to biologics, because biosimilars are similar or highly similar to the original biologic, but not identical.

Indeed, in the chemical pharmaceutical industry, a competing manufacturer may be able to reproduce an original drug with such a high degree of similarity as to make it all but indistinguishable from the original. Bioequivalence between original and generic can be established by relatively simple, cheap, standardised methods. Once bioequivalence is established, all of the safety and efficacy information in relation to the original drug will be automatically applicable to the generic. There are obvious cost-saving elements, for example, there is no need to carry out the initial research to identify the active substance, or to prove its safety and efficacy by clinical trials. This enables generics to be many times cheaper than the original drug.³³

The case for therapeutic equivalence is not so clear-cut for biosimilars. Competing manufacturers typically do not have access to the original biological system used in the manufacturing process, and data from patent disclosures is invariably insufficient to allow the reproduction of the same system. Instead, a new method needs to be developed to produce a similar medicine.³⁴ The applicability of original clinical data to the biosimilar will depend on the degree of similarity achieved. Different regulators deal with this issue in different ways, and abbreviated approval pathways are available for biosimilars in many jurisdictions. The cost-saving opportunity is not the same in proportions as in case of generics, as a certain degree of clinical evaluation is always required. However, due to the high cost of biologics, even if the relative price reduction is smaller as compared to generics, it can still be significant in absolute terms.³⁵

A. Clinical data as a public good or the justification for data exclusivity in biologics

Safety and efficacy data of a medicine may be classified as information and/or knowledge. Such valuable intangible goods are technically inexhaustible in the sense that they can be shared, copied, or used an unlimited number of times. The benefits arising from the use of this type of good are intrinsically non-exclusive, unless excludability is granted by law. In this sense a drug dossier, i.e. the compilation of safety and efficacy data that is required for marketing authorisation purposes, may be considered a public good for the purposes of IPRs.

³³ “FDA estimates total cost-savings over one full year after each generic approval in 2017 to be \$16.0 billion.” U.S. Food & Drug Administration (FDA), *Estimating Cost Savings From Generic Drug Approvals In 2017* (Report, 2017) 2.

³⁴ For an interesting argument as to why biologic manufacturers should be compelled to disclose their proprietary cell-lines, see Lisa Diependaele, Julian Cockbain and Sigrid Sterckx, 'Similar or the Same? Why Biosimilars are not the Solution' (2018) 46 *The Journal of Law, Medicine & Ethics* 776.

³⁵ Deborah Gleeson and others, 'Financial costs associated with monopolies on biologic medicines in Australia' (2019) 43 *Australian Health Review* 36.

One way in which public goods have been protected traditionally, is simply by keeping them confidential. The concept of trade secrets or confidential information has been around for centuries. However, in the case of clinical data this type of protection is not perfectly suitable. It is not possible for a manufacturer to keep the data secret, because claims must be made as to the medicine's safety and efficacy, which is typically only allowed if a regulatory agency is satisfied that those claims are substantiated by clinical data submitted in the dossier. Furthermore, even if the regulatory agency treats the submitted information in the strictest confidence, the mere fact that marketing approval was granted on the basis of the clinical data, may be referred to by a third party without having to have any access to the dossier.

Indeed, a marketing authority may not require the submission of any evidence of safety and efficacy, but simply rely on the mere fact of approval by a foreign authority in another jurisdiction.³⁶ However, even where such evidence was required for the approval of the first market entrant and confidentiality is maintained, a second entrant may still take advantage of prior approval. This point was settled in the Federal Court of Appeal in Canada, where it was decided in the context of the Canadian regulatory regime, that where a generic manufacturer that applies for marketing approval for a follow-on product and has demonstrated bioequivalence to an original product which has already been granted such approval, the marketing authority need not "examine or rely upon" the confidential data previously filed by the first applicant.³⁷ This interpretation has been supported by leading scholars.³⁸

Consequently, if the clinical data is to be protected, specific legislation is required for that purpose. Data exclusivity is a form of protection that creates an artificial temporary barrier that enables the exclusive use of the submitted data. Arguably, the law must define what constitutes "use" in order to avoid the situation outlined above. As will be discussed below, many FTAs specifically state that where the parties are obligated to protect clinical data, they are also not to allow the granting of marketing approvals for biosimilars based on the protected data or on prior approval.

The US and EU have long since introduced IP legislation to protect drug dossiers by granting exclusive rights to the use of the information. These countries have been instrumental in the creation of many FTAs that aim to export these IP rules to many other countries. Exclusivity is typically associated with traditional IPRs that protect public goods such as patents and copyright where the law creates temporary excludability for the creators.

However, it does not follow from the public nature of test data that its creators have to be granted exclusive rights, unless such a right is required as an incentive to create the test data. The most common argument for the protection of clinical test data is rooted in the "incentive theory", which holds that it is in the best interest of society to offer reward to inventors and creators in the form of a period of excludability to incentivise innovation and creation.³⁹ However, clinical data in itself is not an end product with intrinsic value. It is the medicine that embodies the innovation, and its market

³⁶ For example, Drugs and Cosmetics Rules 1945 (India), s 122-A(2); Law No 6,360/76 (Brazil) art 18.

³⁷ *Bayer Inc v Canada (Attorney General)* [1999] 87 CPR (3d) 293.

³⁸ See for example Carlos María Correa, *Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement* (Oxford University Press 2007) 384; Jerome H. Reichman, 'The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?' in Pedro Roffe, Geoff Tansey and David Vivas-Eugui (eds), *Negotiating Health Intellectual Property and Access to Medicines* (Routledge 2012) 142.

³⁹ This is reflected in TRIPS art 7.

value depends on substantiated claims of safety and efficacy, which are prerequisite to the marketing of a drug. Consequently, it is unlikely that test data would not be created without proper incentives.

Also, notwithstanding the theoretical arguments regarding the IP in clinical data, and its similarity to traditional IPRs, such as patents, the current international standard for the protection of clinical data stems from its undisclosed nature, rather than its inherent properties. Unlike patent rights attached to inventions, where patentability depends on whether “they are new, involve an inventive step, and are capable of industrial application”,⁴⁰ which are inherent properties, clinical data is only protected insofar as it is undisclosed, which is an external factor.

Article 39.3 of TRIPS is currently the only multilateral standard for the protection of clinical data, and it is formulated as part of the unfair competition framework. The rationale behind protection against unfair competition is different from that of IPRs that create temporary monopoly.

Arguably, it is the role of patents to incentivise the development of new drugs, and clinical data is an inseparable part of that development, therefore it seems illogical to claim that test data needs a *sui generis* protection regime. Certainly, in case of chemical drugs, patents provide powerful exclusive rights.⁴¹ Traditional chemical drug patents are, like any other patent, prone to legal challenges, but they do not lend themselves to circumvention in the sense that the subject matter can be accurately described and protected.⁴²

By contrast, representatives of the biologics industry argue that patents do not afford similarly good protection for biologics.⁴³ They cite a number of reasons for this: for example, they name the complex nature of the subject matter, which entails that these new compounds can only be partially protected by a “patent suite”.⁴⁴ Also, unlike chemical compounds, biologics are often impossible to describe in such an exact way as to be patentable, instead the protection is for the process of production rather than the resulting compound.⁴⁵ Data exclusivity, they argue, helps complement patent protection.⁴⁶

Data exclusivity can indeed stand in for patent protection and stymie legal challenges for a given period of time. It may also be available even if the subject matter is unpatentable, for example, because of a lack of innovative step. The industry looks at this feature of data exclusivity favourably, arguing that biologics often do not meet patentability criteria for technical reasons. However, critics may point out that patent laws have evolved to incentivise innovation that benefits society and if a product does not meet the criteria then it does not deserve protection.

Indeed, patent law is predicated on the idea of mutual benefit for innovator and society alike. The innovator is rewarded by an exclusive right to benefit from the innovation in return for disclosing the patent. Disclosure of the details of the innovation greatly benefits society as it facilitates further

⁴⁰ TRIPS art 27.1.

⁴¹ TRIPS art 28.

⁴² Although competition amongst chemical drug manufacturers has its own characteristic issues. See, for example Aidan Hollis, 'Me-too drugs: is there a problem?' (*WHO Commission on Intellectual Property Rights, Innovation and Public Health*, 2004) <https://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs_Hollis1.pdf> accessed 08 July 2020.

⁴³ Biotechnology Innovation Organization (BIO), *A Follow-On Biologics Regime Without Strong Data Exclusivity Will Stifle The Development Of New Medicines*.

⁴⁴ Deloitte, 'Avoiding no man's land: potential unintended consequences of follow-on biologics' 6.

⁴⁵ Ibid.

⁴⁶ Henry Grabowski, 'Data exclusivity for new biological entities' (2007) 8 Duke University Department of Economics Working Paper 2.

research and development. Data exclusivity rewards the recipient of the marketing approval, without requiring the disclosure of any information about the product which, at least in theory, could be utilised for further innovation for the benefit of society.

To address this, proponents of regulatory exclusivity, as opposed to patent protection, have argued that market exclusivity could be used instead of data exclusivity, which would allow (although perhaps not mandate) full disclosure of any clinical or manufacturing information, for the benefit of society, while retaining market monopoly.⁴⁷

Further, data exclusivity has the benefit of giving greater certainty to investors in terms of return on investment. One of the shortcomings of patents is that a candidate substance has to be patented at an early stage of development, at a time when there is considerable uncertainty as to when the product can be placed on the market. One consequence of this is that the length of effective patent protection cannot be accurately estimated. It can also lead to an unhealthy incentive for innovators to turn to projects that require less research and development to maximise the length of market monopoly. In contrast, the period of data exclusivity starts from the marketing approval and its length is certain and independent from the research, development and clinical trial timeframes.

B. The regulatory nature of data exclusivity

Data exclusivity, as a form of data protection, has its origin in trade secrets. This is illustrated by its purpose to protect clinical data against “unfair commercial use”, as is stated in various legal texts.⁴⁸ Further, under the TRIPS Agreement, data protection appears under Section 7, Protection of Undisclosed Information, which arguably elevates data protection to the level of other traditional IP laws. However, during the negotiation of the TRIPS Agreement, many countries expressed the opinion that trade secrets are not a category of IP and opposed their inclusion in the Agreement.⁴⁹

Critics have also pointed out that, although data protection is related to trade secrets, data exclusivity, being one step removed from data protection, should be considered a concept independent from traditional IP laws.⁵⁰ The regulatory nature of data exclusivity is most distinctive in its administration. As a *sui generis* regime, it operates via a regulatory body which is responsible for granting marketing approvals but is prevented from doing so in relation to a follow-on product as long as the original product is under protection. The involvement of a marketing authority – an extrajudicial body the original purpose of which is to protect the public from potentially harmful, unsafe or ineffective medicines – highlights the question whether data exclusivity should be regarded as an IPR, or rather classified as an “administrative regulatory exclusivity”, used to enforce an underlying IPR.⁵¹ In other words, it is argued that data exclusivity does not, in itself, constitute an IPR.

Traditionally, IPRs were associated with innovation, creation and, generally, intellectual creative efforts.⁵² However, the protection of undisclosed information, as formulated under Art 39 TRIPS, rests

⁴⁷ Maxwell R Morgan, 'Regulation of innovation under follow-on biologics legislation: FDA exclusivity as an efficient incentive mechanism' (2010) 95 Columbia Sci Technol L Rev XI 116.

⁴⁸ See, for example, TRIPS art 39.3, CETA art 20.29, EFTA – Egypt FTA art 3(e) of Annex V, etc.

⁴⁹ *Status of Work in the Negotiating Group MTN.GNG/NG11/W/76* (Chairman's Report to the GNG, 23 July 1990) 1.

⁵⁰ Beata Stepniewska, 'Test Data Protection - generic and biosimilar industry perspective' (WIPO Symposium, Geneva, 8 February 2010).

⁵¹ *Ibid.*

⁵² See definition of IP in the Convention Establishing the World Intellectual Property Organization (as amended, entry into force 26 April 1970) 828 UNTS 3 (WIPO convention) art 2(viii).

on the doctrine of unfair competition. The effect of the protection against unfair competition is not only rewarding creators and honest traders, but also protecting consumers.⁵³ Article 39.1 of TRIPS incorporates Art 10*bis* of the Paris Convention by reference and develops the idea of protection against unfair competition by adding the concept of protection of undisclosed information or trade secrets.⁵⁴ Article 39.3 of TRIPS extends this protection, in a modified version, to pharmaceutical data, however, only to those relating to chemical drugs.

It should be noted that Art 39.3 of TRIPS creates a distinct *sui generis* regime within the undisclosed information regime. Arguably, the traditional trade secret or confidential information (or undisclosed information) principles are inadequate to protect the type of clinical information that is required for marketing authorisation purposes, because even if the information is kept confidential, the existence of a positive decision based on the confidential information can cause it to lose its competitive value. The information can be “used” without it being disclosed in any detail. Therefore, the main distinctive feature of the data protection provision is that it attempts to address this issue, by mandating the protection of the clinical information against “unfair commercial use”.

Consequently, as far as WTO Members are concerned, the protection against unfair competition entails the protection of undisclosed test data against not only disclosure, but also against unfair commercial use. Members are bound to regard such protection as an IPR. However, it does not follow that market monopoly right must be granted, such as in the case of patents.⁵⁵ It is up to each Member to decide if that is the best way to achieve a healthy market balance.⁵⁶

That said, countries that decided to grant monopoly rights in test data for the benefit of their pharmaceutical industry, such as the US and EU, may make an effort to export these regulations to their trade partners. This has been achieved via bilateral and regional trade negotiations that aimed at reducing other countries’ regulatory flexibility by requiring the implementation of a *sui generis* regime that mandates a period of regulatory data (or market) exclusivity.

Despite the fact that most FTAs refer directly or indirectly to the IPR formulated in Art 39.3 of TRIPS, the majority of FTAs effectively replace the flexible TRIPS provision by superimposing a regulatory regime that goes well beyond the minimum requirements that flow from the principles of protection against unfair competition. Data exclusivity and market exclusivity are better characterised as

⁵³ Christian Riffel, *Protection against unfair competition in the WTO TRIPS Agreement: the scope and prospects of Article 10bis of the Paris Convention for the Protection of Industrial Property*, vol 2 (Brill Nijhoff 2016) 126.

⁵⁴ Paris Convention for the Protection of Industrial Property 1967 (as amended, adopted 28 September 1979, entered into force 3 June 1984) 828 UNTS 305 (Paris Convention).

⁵⁵ “Commentators [...] have noted *ad nauseum* how data exclusivity is a TRIPS-plus demand that has gone beyond the WTO requirements.” Peter K Yu, ‘Data Exclusivities and the Limits to TRIPS Harmonization’ (2019) 45 Florida State University Law Review 18 31. For alternative proposals see, for example, Diependaele, Cockbain and Sterckx, ‘Similar or the Same? Why Biosimilars are not the Solution’ 783; Judit Sanjuan Rius, James Love and Robert Weissman, ‘The Protection of Pharmaceutical Test Data: A Policy Proposal’ 2006) <<http://keionline.org/print/book/export/html/438>> accessed 2019 November 11; “The Compensatory Liability Option” Jerome H. Reichman, ‘Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective’ UNCTAD-ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning, 14 <https://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf> accessed 29 April 2019.

⁵⁶ Carlos M. Correa, ‘Flexibilities provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights’ (2018) 96 World Health Organization Bulletin of the World Health Organization 148.

regulatory exclusivities promulgated as a method of enforcement of an underlying IPR, rather than IPRs in themselves.

Naturally, industry representatives whose purpose is to advocate for research based pharmaceutical innovators disagree. According to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the requirement that a follow-on manufacturer must not rely on the clinical data submitted by the first applicant for a period of time – which is the definition of an exclusive right to that particular use of the data – is “reflected” in the concept of protection against unfair commercial use.⁵⁷ This line of argument generally revolves around the definition of “use” of the clinical data and asserts that when a market authority approves a follow-on product while relying on the first entrant’s dossier, what the market authority does constitutes “use”.⁵⁸

If this point was conceded, then it amounts to a strong basis for the argument that the internationally accepted standard of data protection, as expressed in Art 39.3 of TRIPS not only allows but requires data exclusivity. Then the “fairness” requirement would arguably act as a limiting factor on the exclusive right to rely on the data for the purposes of marketing approval. It would follow that the multilateral standard of data protection is a type of IP protection, which entails an exclusive right to the use of that data, for a period of time.

However, there are at least two reasons while this logic may fail. First, it starts with the premise that reliance constitutes use, which is not a generally accepted interpretation, second the drafting history of the TRIPS Agreement shows that drafts versions of the provision that contained direct reference to exclusivity were rejected by the negotiators.⁵⁹

As will be discussed below, various FTAs and regional agreements formulate data protection in ways that depart from the TRIPS standard to varying degrees. On the extreme certain FTAs (e.g. US-Singapore FTA) divorce data protection from trade secret or undisclosed information regimes by omitting all the terms that could potentially create a connection. These should be considered purely regulatory exclusivities, which prescribe a certain period of market exclusivity without any discernible justification. Indeed, in some regulatory exclusivity regimes the submission of clinical data is the sole eligibility criterion for market protection.

In case of biologics, the above dilemma whether data protection is an IPR or merely a regulatory regime, is even more pronounced, since Art 39.3 of TRIPS does not apply to biologics, therefore no internationally agreed IP has ever been created in clinical data relating to biologics. Consequently, it is more difficult to argue the existence of such an IPR.

C. The origins of data protection

The protection of clinical data emerged in the US and the EU as a consequence of market regulations aimed to protect public health, which, incidentally, tended to stifle competition. In response to this side-effect further regulations were introduced to restore competition. As is often the case with market regulation that influences the playing field, further regulations were required to find the right balance for healthy and fair market competition. It is not surprising, therefore, that the regulatory

⁵⁷ IFPMA, 'Data Exclusivity: Encouraging Development of New Medicines' (*International Federation of Pharmaceutical Manufacturers & Associations*, July 2011) 6 <https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_2011_Data_Exclusivity__En_Web.pdf> accessed 18 July 2020.

⁵⁸ As mentioned above, in *Bayer v Canada* this point was specifically argued, and the court disagreed.

⁵⁹ Nuno Pires de Carvalho, *The TRIPS Regime of Antitrust and Undisclosed Information* (Kluwer Law International 2008) 243.

nature of data protection is so prominent, while its status as IPR is a relatively new and controversial development.

Historically, no clinical studies, or at least none which we would recognise as clinical studies today, were conducted to determine safety and efficacy in medicines.⁶⁰ However, as soon as regulations were put in place to protect public health, clinical data that prove the safety and efficacy of a medicine became valuable. Indeed, pharmaceutical companies in the US regarded clinical data substantiating the safety and efficacy profile of their product proprietary information and the US regulator treated such information as a trade secret.⁶¹

One of the reasons for the existence of data exclusivity regimes in developed countries, where the medicines market is typically heavily regulated, is that competition is facilitated via an abbreviated pathway to market authorisation which is specifically put in place by the government to encourage follow-on entry to the market. Therefore, in developed countries, particularly in the US, there could be no generic or biosimilar competition without a specific mechanism for follow-on entry.

Setting the regulatory foundation for market entry (and hence competition) in the case of generics is relatively straightforward. The regulators typically require that the generic shows chemical identity with the original drug and highly similar bioavailability, based on standardised tests.⁶² This can be applied to all chemical drugs across the board, typically without need for extra, drug-specific studies.

However, there is a significant difference in the complexity of regulatory regimes that enable generic competition, on the one hand, and biosimilar competition, on the other hand, due to the inherent difficulties in producing follow-on biologics that are so highly similar as to qualify as a generic. A robust regulatory system is prerequisite to competition on the biologics market.

As seen in the US and EU models, in general, there is a high-level regulation in place that allows less-than-identical follow-on products to make references to another previously authorised product, despite the fact that similarity can only be shown to a certain degree. What data can be relied on, and to what degree and what must be produced by a second applicant depends on more detailed guidelines, developed pursuant to a higher-level regulation, and a judgment call in the specific case on the part of the market approval authority.⁶³

In terms of data protection, it may be argued that the lower level, detailed regulations and guidelines are immaterial in the sense that as long as any extent of reliance on the original products' clinical information is necessary for a follow-on manufacturer, data protection remains a crucial barrier to market entry.

⁶⁰ Until the tragic events related to Thalidomide, see Phillip Knightley, *Suffer the Children: the Story of Thalidomide* (Carlton Books Limited 1979).

⁶¹ Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (2011) 260.

⁶² European Medicines Agency, 'Biosimilar medicines: Overview' (EMA Official website, 2019) <<https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview#biosimilar-development-and-approval-in-the-eu-section>> accessed 12 July 2020; U.S. Food & Drug Administration (FDA), 'Biosimilar Development, Review, and Approval' (FDA Official website, 2017) <<https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval>> accessed 12 July 2020.

⁶³ "The general principles to be applied [for similar biological medicinal products] are addressed in a guideline taking into account the characteristics of the concerned biological medicinal product published by the Agency", Directive 2001/83/EC Annex I, Part II, s 4.

The complex regulation, however, does introduce significant uncertainty on the market as competition becomes dependent on whether and to what degree the regulatory regime will allow market entry of competing products, with regulators being forced to look at each application and decide on a case-by-case basis.

The EU biosimilar regulatory pathway has evolved over a number of years. Follow-on biologics were first explicitly allowed in 2001.⁶⁴ The current abridged procedure which requires a less-than-full but still substantial dossier, including additional information determined individually, has gone through many amendments and updates.⁶⁵

D. The role of data protection

When a drug is developed for the first time, its safety and efficacy profile must be established. As a consequence of tragic events in the history of medicine, today, every sensible regulator requires clinical trials to be conducted and the resulting data to be submitted for evaluation.⁶⁶ Marketing approval will generally only be granted if the approval authority is satisfied that the submitted data supports the claims made by the manufacturer as to the drug's effects and its safety for use in the target population.

Innovator companies must compile the required data by conducting clinical trials. Since clinical trials are expensive but necessary to substantiate therapeutic and safety claims, the gathered information is of utmost value to the innovator company. However, the information must be disclosed to the regulatory agency for independent evaluation. Even if the agency keeps the dossier confidential, the decision to grant marketing approval will become a matter of public record as soon as the drug appears on the market.

A positive decision and subsequent marketing of the product serve as proof for the medicine's safety and efficacy. Thus, it may become possible for a second entrant to manufacture the same drug and, instead of re-creating the clinical data, simply establish that the two drugs are essentially the same and refer to the data gathered for the original application. This leads to a loss of value in the original dossier, which is a consequence of its submission for approval. That is, unless there is a mechanism in place to keep the data protected. Data protection provisions purport to do that.

Innovator companies have argued, generally quite successfully, that the safety and efficacy data gathered from clinical trials are exclusive property of the company. Data protection therefore can arguably be offered by granting exclusive rights to the use of the data, thereby preventing follow-on manufacturers from benefiting from the existence of that data. Data exclusivity provisions typically offer a term of protection, varying in length, depending on the country.

Data protection in the form of data exclusivity has been criticised for its stifling effect on innovation and competition. Unlike patents, where the protected subject is fully disclosed for public benefit, data exclusivity precludes the use of the clinical data by potentially competing parties. On the other hand, it may be argued that, since clinical data is not required to be disclosed in a medicine patent, data

⁶⁴ Ibid.

⁶⁵ The latest guideline on biosimilars was published in 2014, see European Medicines Agency, *Guideline on similar biological medicinal products CHMP/437/04 Rev 1* (23 October 2014); See also Martin Schiestl, Markus Zabransky and Fritz Sörgel, 'Ten years of biosimilars in Europe: development and evolution of the regulatory pathways' (2017) 11 *Drug Des Devel Ther* 1509.

⁶⁶ For the most detailed medico-legal history of the Thalidomide-induced birth defect crisis see Knightley, *Suffer the Children: the Story of Thalidomide*.

protection benefits the public in that the innovator makes the clinical data available to the public, as long as an exclusivity provision provides security against the use of the data by competitors.

However, the argument that innovator companies desire market protection or market exclusivity in order to re-coup the money invested in the development of the original drug and, purportedly, the cost of compiling the safety and efficacy profile, does not justify the need for data exclusivity (since market protection can be directly mandated without involving clinical data).

On the multilateral level, the formulation of Article 39.3 of TRIPS reveals, in principle, the commonly accepted purpose of data protection, at least in relation to chemical pharmaceuticals. As will be discussed in more detail later, the purpose of data protection is to reward the efforts of generating safety and efficacy data. However, depending on the interpretation of “protection”, implementing data protection provisions has a number of ramifications.

Article 39.3 of TRIPS is one of the most controversial provisions of WTO law, the meaning of which has been analysed and explained many times by academics and professionals. At the peril of losing some of the nuance of those analyses and explanations, one can reduce the arguments to two opposing views. Under the first one, which one may call the “lenient” view for its tendency to allow for a higher level of regulatory freedom, Article 39.3 is interpreted strictly, and it is argued that the provision sets a low threshold for the level of protection required, for example, by not requiring a period of exclusivity.⁶⁷

The opposing view, which one may refer to as the “restrictive” view for its tendency to reduce regulatory freedom, interprets the provision in a wider context, arguing that there is an implied requirement of a higher level of data protection, for example, five years of data exclusivity.⁶⁸

There are more nuanced differences in the interpretive exercise, ranging from no exclusivity with protection afforded only to “required” data and only against dishonest practices, all the way to five (or more) years of data exclusivity with protection against all forms of use of or reliance on the data, granting effective market exclusivity.

Clearly, the consequences of adopting the lenient interpretation are not as onerous as those of the restrictive interpretation. The latter, at least in principle, can lead to delayed market entry of generic products, and a more reliable and stable market for the original brand product. Typically, developing countries take the lenient view, while developed countries with a significant innovative pharma industry tend to adopt the restrictive approach. This is apparent in the different domestic models. Further, it is characteristic of the US and EU trade representatives to vigorously promote their restrictive approach in negotiations, resulting in the adoption of ever higher levels of data protection in trade agreements.

In the following subsections I will discuss the relationship between data protection and data exclusivity, their role in the development of biologics and chemical drugs, and, finally, I will explain some of the prevalent data protection models at the domestic level.

⁶⁷ Yu, 'Data Exclusivities and the Limits to TRIPS Harmonization' 31.

⁶⁸ Office of the General Counsel, US Trade Representative, *The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3* (Unattributed paper for submission in bilateral discussions with Australia, 1995).

1. Data exclusivity vs data protection

Data exclusivity is a particular instance of data protection by way of creating exclusive rights to the use, and benefits arising from the use, of pharmaceutical test data. Data exclusivity is not the only known form of data protection, rather, it is an extreme example of it. The lack of consensus as to whether exclusive rights are necessary for the appropriate protection of test data is generally due to the fundamental disagreement amongst commentators as to what kind of activity data is meant to be protected against. As discussed later, the question typically arises in the context of the interpretation of Art 39.3 TRIPS.

The first examples of regulatory regimes for data protection were data exclusivity provisions. The US lead the way on the domestic level by enacting the Hatch-Waxman Act in 1984, which was followed by the EU in 1987.⁶⁹ On the international plane, NAFTA, ratified in 1993, introduced the first regional standard, also in the form of exclusive rights.⁷⁰ Subsequently, the TRIPS Agreement came into force, as part of the WTO Agreement, which introduced the first multilateral standard for pharmaceutical test data protection.⁷¹

It certainly seems a foregone conclusion that data exclusivity regimes for chemical pharmaceuticals are *allowed* by Art 39.3 TRIPS. However, governments of industrialised countries insist that data protection can only be achieved through data exclusivity, therefore it is a *requirement* under Art 39.3.⁷² This is a contentious issue that has not yet been decided authoritatively.⁷³

The issue of data protection and data exclusivity is even more problematic in relation to biologics. One of the least contested issues about the interpretation of Art 39.3 is that it refers specifically to *chemical* entities rather than pharmaceuticals generally. The conclusion that biologics are outside the section's scope holds up to scrutiny.⁷⁴

As discussed above, the traditional incentive theory positing that IPRs are necessary to offset the upfront costs of creating intellectual works cannot be readily applied to the creation of clinical data. Since pharmaceutical companies are required to prove the safety and efficacy of their products, it is doubtful that data protection is necessary to incentivise the development of this information. It is almost self-evident that such clinical data would be produced even in the absence of legal protection.

That said, even though the incentive theory cannot fully justify their existence, data protection and data exclusivity do exist. A better explanation can be found in the fact that, as will be discussed in the following sections, the effect of these IPRs is a minimum period of market protection for the original drug. Indeed, this market-protective effect provides an important point of distinction between the regulation of biologics and chemical drugs.

⁶⁹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub L No 98-417, 98 Stat 1585 (Hatch-Waxman Act).

⁷⁰ NAFTA arts 1711.5 and 1711.6.

⁷¹ TRIPS art 39.3.

⁷² Office of the General Counsel, *The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3*.

⁷³ The provision has not yet been interpreted by WTO Panels or the Appellate Body.

⁷⁴ Owais H. Shaikh, *Access to medicine versus test data exclusivity: safeguarding flexibilities under international law* (Springer 2016) 82-83.

2. Current data protection provisions

a) US model

The US regulatory model for data protection for pharmaceuticals separates chemical and biological pharmaceuticals. The prevalent view is that the traditional pharma industry and the relatively new biotech industry differ in fundamental ways, which warrants fundamentally different regulations.⁷⁵

(1) The Hatch-Waxman Act

In case of chemical pharmaceutical products, data protection came about in the form of a data exclusivity period under the Hatch-Waxman Act in the US. The Drug Price Competition and Patent Term Restoration Act, as it is formally known, brought about fundamental changes in the chemical pharmaceutical drug market. The Act predates the TRIPS Agreement by ten years and the former is not in fact an interpretation of the latter; however, the approach to data protection under the Hatch-Waxman Act is a proper model of the “restrictive” interpretation of Article 39.3.

Data exclusivity introduced by the Hatch-Waxman Act was part of a compensation package for the innovative pharma industry. The main purpose of the Act was to facilitate competition on the pharmaceutical market by creating an abbreviated regulatory approval pathway for generic medicines. For the first time in the US, it became possible for generic manufacturers to put on the market medicines that were copies of a brand-name drug, without having to complete clinical trials to establish safety and efficacy. Instead of having to complete an entire dossier, generic drugs are only required to prove a level of similarity with the original drug.⁷⁶

An option for innovator companies to extend the patent protection on their original drug by up to five years, up to a maximum of 14 years, and a five-year data exclusivity, delaying generic competition, were offered to innovators as a trade-off for enabling price competition.⁷⁷ Undoubtedly, in most cases the exclusivity period overlaps with the patent protection period; however, the provision still serves as a minimum guaranteed market exclusivity for the original drug. In short, the Hatch-Waxman Act established an exclusive marketing period for innovators of at least five years, and up to 14 years.

(2) The Biologics Price Competition and Innovation Act (BPCIA)⁷⁸

The above was not applicable to biological pharmaceuticals, because it is not possible for follow-on biologics to fulfil the criteria to be classified as a generic.⁷⁹ In the traditional domain, similarity between an original and a generic medicine is so high that the residual differences have negligible clinical effect. Biotechnology, by contrast, involves complicated procedures the end product of which is enormously more complex than a traditional chemical molecule and its structure is highly dependent on the particulars of the process. Consequently, creating an exact copy of a biologic is not practicable (which is why follow-on biologics are not called generics but biosimilars).

Hence, in 2009 the BPCIA was passed to amend existing federal law introducing an abbreviated licensure pathway specifically for biosimilars.⁸⁰ Under this regulatory regime, a biosimilar may be

⁷⁵ Deloitte, 'Avoiding no man's land: potential unintended consequences of follow-on biologics'.

⁷⁶ Generics are required to be bioequivalent to the original drug, which is a very high level of similarity.

⁷⁷ 35 USC § 156 (1984).

⁷⁸ The Biologics Price Competition and Innovation Act of 2009, Pub L No 111-148, 124 Stat 804 (BPCIA).

⁷⁹ Although there are degrees of difference, e.g. under the US regime some biosimilars may be classified as “highly-similar” whereas others may be “interchangeable”. To date, however, there have been no biosimilars in the latter class.

⁸⁰ The BPCIA amended the Public Health Service Act of 1944, 42 USC § 262 (2010) s 351 (PHSA).

eligible for licensure with a partial dossier of safety and efficacy data, provided that a high level of similarity to a reference product that has previously been approved for marketing is demonstrated.⁸¹

Similarly to the compensation offered to chemical drugs under the Hatch-Waxman Act, the BPCIA grants certain market exclusivities to qualifying innovative biologics, such as a 12-year market exclusivity during which no biosimilars intending to reference the product may be approved.⁸² Overlapping this period, a four-year data exclusivity is also offered, during which biosimilars are barred from submitting applications via the abbreviated pathway.

Interestingly, despite the US Trade Representative's push to export the US data exclusivity regime to trade partners, the issue of high drug prices due to IP protections has become a constantly recurring topic in the US. The affordability of medicines has been part of the ongoing election campaign in the US.⁸³ Increasing burden on the federal budget due to high spending on prescription medication has prompted calls for clear guidelines for the relevant authorities to exercise march-in right in an effort to reduce the burden.⁸⁴ Under the Bayh-Dole Act,⁸⁵ in certain narrowly defined circumstances, the US government may force certain patent holders to grant additional licenses in order to address non-use or unreasonable use of certain inventions.⁸⁶

Following the initial agreement, Members of Congress have expressed concerns over the data exclusivity provision of the USMCA, which was pending ratification in the US, and if ratified, would have locked in a minimum of ten years of data exclusivity for biologics with Congress losing its ability to lower it.⁸⁷ The Democratic majority of the House of Representatives eventually succeeded in persuading the White House to amend the proposed text, removing the ten-year data exclusivity requirement for biologics, citing their extraordinary price as the reason for the change.⁸⁸ The revised version of the agreement was said to serve as a model for future US trade agreements. This may

⁸¹ Biosimilars may rely on the safety and efficacy data of a reference product: 42 USC § 262(k)(2)(A)(i)(I).

⁸² 42 USC § 262(k)(7)(A), see also Charles W Mitchell, Jennifer H Roscett and Shana Cyr, 'Dead Zone: Are Your Biological Products Ready For FDA's Regulatory Transition?' *American Pharmaceutical Review* <<https://www.americanpharmaceuticalreview.com/Featured-Articles/337397-Dead-Zone-Are-Your-Biological-Products-Ready-for-FDA-s-Regulatory-Transition/>> accessed 07 May 2019.

⁸³ Yasmeen Abutaleb and Josh Dawsey, 'White House races to come up with health-care wins for Trump's campaign' *Washington Post* (U.S. 1 August 2019) <https://www.washingtonpost.com/health/trump-to-unveil-drug-price-health-initiatives-in-walk-up-to-2020/2019/07/31/f4adc4de-af1a-11e9-8e77-03b30bc29f64_story.html> accessed 9 July 2020; Pete Buttigieg, 'Affordable Medicine for All: A Plan to Slash Drug Prices and Boost Medical Innovation' (*Presidential Campaign Brochure*, 2019) <<https://peteforamerica.com/policies/affordable-medicine/>> accessed 1 February 2020; Rohan Chalasani, Julie M. Donohue and Walid F. Gellad, 'Prescription 2020: Democratic Candidates And Drug Pricing' (*Health Affairs Blog*, 2019) <<https://www.healthaffairs.org/doi/10.1377/hblog20190826.689286/full/>> accessed 9 July 2020.

⁸⁴ Kimberley Leonard, 'Budget Breakers' (*US News*, 24 September 2015) <<https://www.usnews.com/news/the-report/articles/2015/09/24/expensive-drugs-a-drag-on-consumers-and-government>> accessed 18 July 2020; Kimberley Leonard, 'Can the Government Already Control Drug Prices?' (*US News*, 11 January 2016) <<https://www.usnews.com/news/articles/2016/01/11/congressional-democrats-urge-nih-to-act-on-drug-prices>> accessed 18 July 2020.

⁸⁵ Jacob Parmuk, 'House Democrats and the White House have a deal to move forward with USMCA trade agreement' (*CNBC*, 11 December 2019) <<https://www.cnn.com/2019/12/10/house-democrats-and-trump-administration-reach-usmca-trade-deal.html>> accessed 18 July 2020.

⁸⁶ Patent Rights in Inventions Made with Federal Assistance, 35 USC § 203.

⁸⁷ *Letter from Representative Jan Schakowsky et al. to Robert E. Lighthizer, U.S. Trade Representative* (Open letter, 11 July 2019) <<https://schakowsky.house.gov/uploads/lighthizermeds.pdf>> accessed 1 February 2020.

⁸⁸ Parmuk, 'House Democrats and the White House have a deal to move forward with USMCA trade agreement'.

indeed mean that the US stance on data exclusivity has changed in the past few years with regards to biologics to the effect that the US will not seek to mandate more than five years of data exclusivity, and perhaps that there will be no distinctions made between chemical drugs and biologics in this respect.

b) EU model

Although the EU followed the US in its footsteps in setting up a data exclusivity regime, the reasons for doing so were different, which also explains some of the differences in the resulting regulatory scheme. The exclusivity period was to serve in lieu of patent protection in some member states where patents were not available for pharmaceuticals.⁸⁹

Whereas the US had virtually no generic competition before introducing the Hatch-Waxman Act, European nation states had had varying approaches to allowing generics on the market before the data exclusivity regime was set up. A form of “abridged procedure” to marketing authorisation was generally recognised, where regulators did not require a full dossier from generic applicants.⁹⁰ A harmonised marketing approval procedure, including a compensatory data protection regime has evolved over time in the EU. However, unlike in the US, the EU regime in its current form makes no distinction between traditional chemical and biologic medicines for the purposes of data protection.

Initially, influenced by the US developments of 1984 in this area of law, the first version of the EU data protection regulation was put in place in 1987.⁹¹ This regulation, unlike its US counterpart, referred to biotechnological products specifically, providing a higher level of protection for these and other high-technology medicines. The protection was formulated as a data exclusivity period of six years for traditional pharmaceutical products and ten years for biologics.⁹² Thus the EU became the first to introduce data exclusivity for biologics.

In 2001 a harmonisation of national regulations was initiated, and after long deliberations the current “8+2+1” system was established.⁹³ Importantly, in the current system the same rules apply to all pharmaceuticals across the board.⁹⁴

Firstly, the regulation provides for an eight-year period of data exclusivity period starting from the date of the first marketing approval. This is a *de facto* market exclusivity period during which no generics or biosimilars referencing the original can be approved. Furthermore, follow-on products cannot be tested on human subjects, since the necessary safety data is exclusive to the first applicant.

⁸⁹ Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* 261.

⁹⁰ Judit Sanjuan Rius, 'U.S and E.U Protection of Pharmaceutical Test Data' CPTech Discussion Paper - No 1 <<http://cptech.org/publications/CPTechDPNo1TestData.pdf>> accessed 08 May 2019.

⁹¹ Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [1987] OJ L15/36.

⁹² Directive 2004/27/EC. For further discussion, see Sandra Adamini and others, 'Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities' (2009) 34 *Journal of Health Politics, Policy and Law* 979 989-92 and Trevor Cook, 'Data protection and market exclusivities for pharmaceuticals in the EU' (2014) 16 *Pharmaceuticals Policy and Law* 19 20-22 Council Directive of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L136/34.

⁹³ Directive 2004/27/EC.

⁹⁴ For a detailed analysis see Cook, 'Data protection and market exclusivities for pharmaceuticals in the EU' 22-25.

After the first eight years of data exclusivity a further two years of marketing exclusivity is granted. Once the data exclusivity period is over generic and biosimilar manufacturers can start the necessary tests and the approval process in anticipation of a product launch at the end of the market exclusivity period.

Lastly, a further one year of market exclusivity may be granted to the first applicant in certain cases if a new indication for the medicine was demonstrated and the necessary clinical trials were successfully carried out.

Thus, the EU data exclusivity regime goes far beyond the minimum requirements laid down in Art 39.3 of TRIPS. This high level of protection that ensures market exclusivity for a long period of time benefits the research based pharmaceutical industry in the EU. However, the social costs of the setting the period of protection at ten years were not taken into account appropriately, according to analysts.⁹⁵ It has been suggested that the decision was heavily influenced by industry lobbyists, while the perspectives of other interested parties, representing the consumers, health professionals, and generic manufacturers was not given their due.⁹⁶

Consequently, it is difficult to make a case that the 8+2+1 exclusivity regime has been formulated in a manner that is “conducive to social and economic welfare, and to a balance of rights and obligations.”⁹⁷ Admittedly, the negative impact cannot be easily measured.

c) Indian model

India has a “new drug” regime that creates results akin to data exclusivity regimes. Under this regime new drugs can only be imported or manufactured with permission of the licensing authority, which in turn requires clinical trial data to be submitted to it for evaluation, unless the licensing authority deems it in the public interest to grant permission “on the basis of data from other countries”.⁹⁸ A drug is considered “new drug” for a period of four years, during which these requirements for import or manufacturing licence stay in place.⁹⁹ These requirements can typically only be fulfilled by the originator companies that conducted clinical trials. Therefore, for a period of four years generic manufacturers may not enter the market. These rules do not distinguish between chemical and biological drugs.

This system creates a relatively low level of market protection for new drugs. It does not create an explicit data protection or data exclusivity regime, but it does seem to fulfil India’s international commitment to IP protection under TRIPS.¹⁰⁰ In fact, India has been described as a shining example of

⁹⁵ Adamini and others, 'Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities' 993.

⁹⁶ Ibid 999.

⁹⁷ TRIPS art 7.

⁹⁸ See Drugs and Cosmetics Rules 1945 (India), Part X-A.

⁹⁹ Drugs and Cosmetics Rules 1945 (India), s 122-E.

¹⁰⁰ Although India is on the USTR Special 301 Report Priority Watch List *inter alia* for “[t]he lack of any effective system for protecting against the unfair commercial use, and unauthorized disclosure, of undisclosed test or other data” Office of the General Counsel, US Trade Representative, 'Special 301 Report on Intellectual Property Protection and Review of Notorious Markets for Counterfeiting and Piracy' (USTR Official website, 2020) 50 <https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf> accessed 19 July 2020.

a TRIPS-compliant developing country.¹⁰¹ Developing countries may find India's restrictive approach to data protection and pharmaceutical patents instructive.

Pharmaceutical companies have long lobbied for better patenting rules on the global scale, which has come to fruition in the TRIPS agreement.¹⁰² Although, India compromised on its strict stance on patenting when it made pharmaceutical products patentable in 2005,¹⁰³ there are significant restrictions still in place, such as the controversial section 3(d) of the Patents Act, stipulating that "a new form of a known substance" is not patentable. These restrictions have been the subject of numerous challenges by pharmaceutical companies.¹⁰⁴

The fierce and relentless opposition to India's patenting rules may prove to be insufficient to sway the country, however developed countries with significant innovative pharma industry presence, such as the EU and US, may seek different avenues to achieve better market protection for their products.¹⁰⁵ That is, developed countries have adopted the strategy of proposing higher level regulatory exclusivities, such as data exclusivity, in FTAs. Indeed, data exclusivity has some advantages over patents, for example it could apply to non-patentable products.

FTA negotiations between India and the EU have come to a stand-still after many rounds, but India stood its ground and refused to introduce more comprehensive or higher levels of data protection.¹⁰⁶ More recently, the issue of extending the market protection period to ten years has come back to the table. However, following the Indian Drug Technical Advisory Board's recommendation against the move, the proposal was not accepted.¹⁰⁷

India is a developing country with a large population and a strong enough economy to safeguard its significant generic and biosimilar manufacturing capacity. Along with other developing countries, such as Brazil, it may prove to be a formidable force against developed countries' efforts to export their IP protection regimes via trade agreements.

d) New Zealand model

New Zealand's approach to data protection is in between the standards established by the US and the EU and those adopted by developing countries such as India. Although a well-industrialised country, New Zealand has no significant domestic innovative pharmaceutical industry, only a small generic production capacity. The country relies on imports in the medical and most technological fields.¹⁰⁸

¹⁰¹ Daniel Acquah, 'Extending the limits of protection of pharmaceutical patents and data outside the EU - Is there a need to rebalance?' (2014) 45 IIC International Review of Intellectual Property and Competition Law 256 271.

¹⁰² See, for example, TRIPS arts 27, 39.3 and 70.

¹⁰³ In line with the recommendation made by the Appellate Body in *WTO India - Patent Protection for Pharmaceutical and Agricultural Chemical Products - Report of the Appellate Body* (19 December 1997) WT/DS50/AB/R.

¹⁰⁴ See for example *Novartis AG v Union of India* (2013 (5) SCALE 12), *Fresenius Kabi Oncology Limited v Glaxo Group Limited* (ORA/17/2012/PT/KOL), *Ajanta Pharma Ltd v Allergan* (ORA/21/2011/PT/KOL).

¹⁰⁵ For the development of this argument see Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* 121.

¹⁰⁶ Acquah, 'Extending the limits of protection of pharmaceutical patents and data outside the EU - Is there a need to rebalance?'.

¹⁰⁷ Bhavik Narsana, Soumyadri Chattopadhyaya and Yashashree Mahajan, 'Clinical Trials and Data Exclusivity: In Search of a Fine Balance' (2017) March 2017 *Pharma Bio World* 10 18.

¹⁰⁸ *New Zealand TPP Intellectual Property Chapter: Horizontal Issues/Overall Structure, General Provisions and Cooperation*.

Under the current laws, New Zealand grants five years of data exclusivity to newly registered innovative medicines.¹⁰⁹ The exclusivity is explicitly extended to biologics.¹¹⁰

During the TPP negotiations New Zealand opposed the US in its endeavour to raise the minimum data exclusivity period for biologics. The original proposal of 12 years was eventually dropped to eight years, with an alternative option of 5 years plus additional measures that deliver a comparable market protection as the eight-year data exclusivity option.¹¹¹ The Ministry of Foreign Affairs and Trade stated that if the TPP comes into force it would not be necessary to amend the current regulations to increase the level of protection for biologics as the TPP requirements “can be met within existing policy settings and practice”.¹¹² Because the TPP-11 countries have suspended said provisions and the issue has been tabled, the question what additional market protection measures might look like has become obsolete for now.

III. A multilateral standard of data protection for biologics?

In this part, I will discuss the emergence of data protection for biologics. I will outline the existing international framework with a view to distinguish between the status of IPRs in relation to biologics and chemical pharmaceuticals. Then, after drawing attention to the mismatch between the underlying IP principles and the prevalent methods of implementation, I will submit that what has been a controversial but defensible outcome for chemical drugs, is far more controversial and perhaps even indefensible for biologics under the current framework.

The basis of this argument is that data protection provisions for chemical pharmaceuticals in domestic law as well as on the international level are framed and supported by WTO law. In contrast, such IPRs for biologics only exist in domestic law and FTAs, but not on the multilateral level. I submit that a multilateral agreement would be desirable, and I will conclude with a synthesis of a hypothetical standard.

A. Emerging standards

Data protection for biologics has never been subject to multilateral negotiations. According to commentators, due to anticipated resistance from developing countries, the US and EU have taken to a non-multilateral approach to export their IP protection standards.¹¹³ Many recent US and EU FTAs have data protection provisions for pharmaceuticals, specifically including biologics, in the form of exclusive rights.

Data protection provisions are consistently being included in the IP chapters of FTAs. Signatory countries that are also Members of the WTO have already accepted data protection as an IP, TRIPS being part of the WTO agreements.¹¹⁴ This is taken a step further in FTAs that mandate the protection of this IP with an exclusive right to the use of the data. However, due to its wording, Art 39.3 of TRIPS

¹⁰⁹ Medicines Act 1981 (NZ), s 23B.

¹¹⁰ Medicines Act 1981 (NZ), s 23A.

¹¹¹ TPP art 18.51(1).

¹¹² Ministry of Foreign Affairs and Trade, *TPP Overview Fact Sheet* 5.

¹¹³ Peter K. Yu, 'The non-multilateral approach to international intellectual property normsetting' (*Research Handbook on International Intellectual Property Law*, Daniel J. Gervais, ed., Edward Elgar Publishing, 2014) <<https://ssrn.com/abstract=2325766>> accessed 15 July 2020.

¹¹⁴ WTO, *Argentina: Safeguard Measures of Imports of Footwear – Report of the Appellate Body* (12 January 2000) WT/DS121/AB/R [81].

does not support the proposition that IP in clinical data relating to biologics has been universally accepted.

It may be accepted that Art 39.3 of TRIPS creates IPRs in test data. However, it only does so in relation to chemical drugs. There is no international authority to support the view that any rights, exclusive or otherwise, pertaining to test data relating to biologics, exist, or that such rights should be considered IPRs.

This point would have to be considered in the hypothetical multilateral negotiations that establish the international standard of data protection for biologics. There is merit in the argument that the nature of clinical data is the same regardless of the constitution of the drug it pertains to. Therefore, the protection of such data should be based on the same principles. On this basis, one may expect a provision similar to Art 39.3 of TRIPS.

However, this proposal fails to consider some important points and recent developments on the international IP landscape. Firstly, in the years after the conclusion of the Uruguay Round, the EU and the US have been actively seeking to ratchet up the standard of data protection. The number of countries committed to such higher standards has to have a bearing on a hypothetical multilateral negotiation. Secondly, if the basis of the standard for biologics is the fact that the nature and purpose of the clinical data is the same to that of chemical drugs, then the level of protection should also be the same. The US, in its domestic regulations as well as in recent regional agreements, namely in the USMCA and TPP, has consistently argued for differential treatment for biologics. A draft of the envisaged USMCA raised the level of protection of data pertaining to biologics to double of the level afforded to chemicals. This suggests a different rationale for the protection.

In any case, a multilateral standard embedded in TRIPS would be desirable from the perspective of dispute resolution. Before 1994, under the GATT 1947 regime, trade restricting measures that were necessary for the enforcement of IPRs were considered barriers to trade but nevertheless allowed under Art XX(d) GATT.¹¹⁵ TRIPS integrated IP into the WTO framework, which reflects the modern view that recognises that the lack of IP protection can lead to illegitimate trade or other trade distortions.¹¹⁶ Thus, trade-restricting measures for the enforcement of IPRs covered by TRIPS are not required to be justified under Art. XX(d). Admittedly, Art. XX(d) contains a non-exhaustive list of IPRs; nevertheless, I have previously suggested that certain enforcement measures of IPRs not covered by TRIPS may not only come within its purview but potentially do not meet the requirements of the exception clause.¹¹⁷

Due to cultural and historical differences, IP regulations have varied widely in different countries. To this day, IP law remains a sensitive issue, left to each country to deal with domestically. It is conceivable that one country may institute certain IP protective measures that its trading partners find objectionable due to its trade-restrictive effects. The IPR, such as data exclusivity for biologics, may be GATT-compliant, but the enforcement measure, such as marketing restriction and the resulting restriction on trade, may be considered excessive. In such a case, the country may face a WTO dispute and may be forced to defend its protective measures before a WTO panel and, without recourse to an existing TRIPS provision, it may need to invoke Art XX(d).

¹¹⁵ General Agreement on Tariffs and Trade (1947) 55 UNTS 194 (GATT 1947); See, for example, *United States: Imports of Certain Automotive Spring Assemblies* (1982) GATT BISD 30S/107 [58]-[60].

¹¹⁶ TRIPS Preamble, recital 1.

¹¹⁷ This is a controversial assertion explored in Hegedus-Gaspar, 'Data Exclusivity for Biological Pharmaceuticals: Is New Zealand in Breach of World Trade Organization Law?' 920.

It is submitted that, should a dispute arise due to the trade-restrictive effect of protective enforcement measures affecting trade in biologics, Art XX(d) may indeed need to be invoked. This could be avoided, and a more predictable environment could be achieved, if data protection for biologics was mandated under TRIPS.

B. Approaching multilateralisation through megaregulation

Apart from bilateral and regional negotiations, large regional agreements, also called megaregionals, such as the CPTPP, have become the preferred forum of furthering the multilateralisation of IP regulations.¹¹⁸ Trade agreements that harmonise economic regulation in an entire region have a profound effect that can reach beyond the region. The TPP was a particularly attractive forum for the US to facilitate the adoption of higher IP standards. If successful, 12 countries with a significant share in the world's economy would have had to implement those standards, including the eight years of data exclusivity, or a comparable level of market protection, for biologics and the erasure of the "considerable effort" requirement. Undoubtedly, the increased level of protection would have negatively affected trade in biosimilars both within and inbound to TPP countries, creating such economic pressure that could possibly have made it unfeasible for some follow-on manufacturers to continue operations.¹¹⁹

Bilateral agreements that contain TRIPS plus provisions are binding on the parties, not only vis-à-vis the contracting parties, but, due to the lack of an economic integration exception in TRIPS, the parties must also extend the higher standards to third parties.¹²⁰ In case of data protection, this is the case almost by necessity, because medicine regulators are not political institutions. The role of enforcing data protection falls on the authority that is responsible for only allowing safe and efficacious medicines on the market. Consequently, barring corruption, such an authority will have one set of rules for medicines regardless of their origin. Decisions of the marketing authority are based on the submitted or referenced clinical data, not on the applicant's country of origin.

However, the weakness of bilateral agreements as compared to a large regional agreement is that, if a country finds that the burden placed on it by a particular FTA is untenable, it may be able to withdraw from it at a relatively low cost, whereas exiting a regional agreement comes at a higher price. Consequently, once a regional agreement is in place, it has a strong cohesive force, and parties will be unwilling to leave it, even if, for example, the IP provisions are onerous. Regional agreements, such as the CETA and the CPTPP, are able to solidify the IP standards they contain, and member countries will be bound to extend those standards to countries outside of the region.

Should a multilateral standard be negotiated that is also contained in a large regional agreement, the parties to that agreement will be disinclined to oppose the inclusion of the higher standard in the multilateral agreement. Thus, IP standards in megaregional agreements become the baseline for future negotiations as far as the parties to the megaregional are concerned.¹²¹

¹¹⁸ See Christian Riffel, *Mega-regionals* (Max Planck Encyclopedias of International Law, 2016) para 92.

¹¹⁹ Rochelle Cooper Dreyfuss, 'Harmonization: Top Down, Bottom Up - and Now Sideways?' in Benedict Kingsbury (ed), *Megaregulation contested: global economic ordering after TPP* (Oxford University Press 2019) 351.

¹²⁰ See Riffel, *Mega-regionals* para 69.

¹²¹ Cooper Dreyfuss, 'Harmonization: Top Down, Bottom Up - and Now Sideways?' 355.

Terms included and defined in trade agreements can be utilised in an interpretive exercise to elicit the understanding of the parties of the meaning of that term.¹²² A megaregional agreement could certainly create a strong interpretive context for the parties. WTO Panels may engage in such an interpretive exercise wherever a dispute involves the correct construction of a term.¹²³ In *Canada – Pharmaceuticals*, the Panel considering the meaning of “legitimate interests” under Art 30 of TRIPS stated that “the term [...] must be defined in the way that it is often used in legal discourse”.¹²⁴ The Panel included in the analysis the use of the term in Art 9(2) of the Berne Convention, as well as referring to its negotiation history, for the reason that this text served as the basis of the relevant part of Art 30 of TRIPS.¹²⁵

Large regional agreements, such as the CPTPP, where a number of countries, representing a significant portion of the trade economy, harmonise their regulations and subscribe to a particular interpretation of a term, may influence the outcome of a WTO dispute where the meaning of that term is in question. Admittedly, this influence may well be insufficient to significantly change the meaning of a term in a covered agreement. The prevalent view of the Appellate Body is that in interpreting the terms of the covered agreements by applying Art. 31(3)(c) of VCLT, one has to exercise caution so as not to impose the contractual intentions of a small subset of WTO members on the entire WTO membership.¹²⁶

As noted above, Art 39.3 of TRIPS contains a number of undefined, vague terms that may need to be interpreted by a WTO Panel in a future dispute. In terms of data protection, however, it is unlikely that, even a large megaregional, such as the CPTPP, can have enough weight for a panel to apply an interpretation of Art 39.3 of TRIPS that broadens its scope so as to include biologics, or to read into the provision a minimum exclusivity requirement.

Nevertheless, should the currently suspended provisions relating to data protection in the CPTPP, come to force, it will become the mandatory standard in all parties. This standard, in turn, can propagate towards all trade partners of the CPTPP membership, due to the combination of the nature of public health and pharmaceutical market regulations, and the formulation of the TRIPS MFN clause.

In the following sections, I will discuss the existing provisions in international law that shape the current status of data protection for biologics. My intention is to elicit the view of the international community on this issue and canvass the current trends and sticking points, which will allow me to draw up a standard of data protection for biologics that has, in my view, the best chance of being accepted multilaterally.

C. Data protection in WIPO

The World Intellectual Property Organisation is a global organisation that promotes and guides IP protection internationally.¹²⁷ Any discussion that is aimed at finding whether or how the protection of pharmaceutical data fits into the WIPO framework, must touch on the question whether data

¹²² Vienna Convention on the Law of Treaties (entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 31.3(c).

¹²³ See, for example, WTO, *Canada: Patent Protection of Pharmaceutical Products – Panel Report* (17 March 2000) WT/DS114/R (*Canada – Pharmaceuticals*) [7.69].

¹²⁴ *Ibid.*

¹²⁵ *Ibid* [7.70].

¹²⁶ WTO, *European Communities and Certain Member States: Measures Affecting Trade in Large Civil Aircraft – Report of the Appellate Body* (18 May 2011) WT/DS316/AB/R (*EC and Certain Member States – Large Civil Aircraft*) [845].

¹²⁷ WIPO Convention art 3.

protection is indeed a type of IPR. The answer to the question is complicated by the fact that data protection is a blanket term that is used to describe a wide variety of concepts, including regulatory regimes. Part of the answer is that not all kinds of data protection can be regarded as IP protection within the meaning of Article 2(viii) of the WIPO Convention.

Article 2(viii) of the WIPO Convention provides that IP includes “protection against unfair competition”. Therefore, if a particular data protection regime is part of such a regulatory framework, then data protection is an IPR according to the WIPO understanding.

However, protection against unfair competition, unlike other IPRs such as patents, does not normally entail exclusive rights and market monopoly. In an attempt to turn data protection into data exclusivity, or rather to introduce market exclusivity in the guise of data protection countries with strong innovative pharmaceutical industry removed data protection from the realm of the unfair competition framework, as evidenced by the FTAs discussed later. The data protection provisions in the discussed FTAs require the implementation of various *sui generis* regimes granting market exclusivity to the right holders.

There are currently no conventions administered by WIPO that deal directly with data protection. The relationship between WIPO and data protection is indirect. Article 10*bis* of the Paris Convention lays down the basic principles of protection against unfair competition. This is developed further under Art 39.1 of TRIPS that introduces the protection of undisclosed information, a term used in place of trade secrets, into international law, as integral part of the unfair competition framework. TRIPS forms part of WTO law,¹²⁸ and, although it integrates the Paris Convention by virtue of Article 2.1 and refers directly to Art 10*bis* in Art. 39.1, it cannot be concluded that data protection is a WTO-conform IPR.

Pharmaceutical test data is merely information, gathered during clinical trials. Although the collection and compilation of such data usually requires considerable investment, the resulting information is still only information, knowledge based purely on observation. Traditional IPRs are generally not applicable to observations, even if they relate to an innovative product. The fact that clinical data is never included in the patents relating to a pharmaceutical product illustrates this point.

Yet, Art 39.3 of TRIPS mandates the protection of pharmaceutical test data on the basis of it being undisclosed, that is, a trade secret. However, it is not generally accepted that trade secrets constitute IP, or that their protection should entail exclusive rights. Further, even if one considered trade secrets IP, it does not follow that it is also an IP according to the WIPO, since there is no explicit reference in Art 10*bis*, or in any other part of the Paris Convention, to trade secrets.

Indeed, by mandating protection against unfair competition, Art 10*bis* protects market-competitors as well as consumers.¹²⁹ It provides for governments to control the market and prohibit dishonest practices that, for example, may cause confusion or mislead the public.¹³⁰ In contrast, the type of protection afforded under Art 39 of TRIPS is solely aimed at the protection of private business. Furthermore, Art 39.3 of TRIPS takes another step away from Art 10*bis* by mandating the protection of undisclosed data against unfair commercial use.

¹²⁸ WTO Agreement art II:2.

¹²⁹ Although the consumer-protective effect of Art 10*bis*(3) may only be incidental, Riffel, *Protection against unfair competition in the WTO TRIPS Agreement: the scope and prospects of Article 10bis of the Paris Convention for the Protection of Industrial Property* 126.

¹³⁰ Paris Convention art 10*bis*(3)(iii).

Consequently, under the current conventions administered by WIPO, the protection of pharmaceutical test data is not mandatory. That said, the majority of WIPO members that are also members of the WTO and bound by TRIPS, are required to protect test data in the course of protecting against unfair competition.

However, since biologics are not covered by Art 39.3 of TRIPS, the question arises how to approach data protection for biologics? Based on the mission of WIPO, which is to enable innovation via effective and balanced IP systems, one has to conclude that the organisation would support the idea of data protection as long as there is consensus among the members that it is indeed a category of IP and the creative benefit outweighs the burden imposed by it.

This touches on the fundamental characteristic of IP, which is that IP is a legal construct. The international community is divided on the question of data protection for biologics and it is unlikely that consensus will be reached on the topic any time soon. Unquestionably, there are costs and benefits associated with granting IPRs, and it each society has to determine where to strike the balance between the two. Different countries with different economies and opportunities will draw the line in different places.

It is submitted that, should the WIPO turn to the question of data protection, it may follow the development formulated under Art 39.1 of TRIPS and mandate the protection of trade secrets from disclosure as integral part of protection against unfair competition. Or it may create a new category of IP along the lines of the proportionality test in Art 39.3 of TRIPS,¹³¹ which provides a rationale for test data to be considered worthy of protection, by virtue of the effort invested in its compilation. Both of these approaches would be in line with the fundamental principles of IP protection. It is further submitted that, since in both of these cases the subject matter of protection is undisclosed test data, there is no reason for WIPO to follow Art 39.3 of TRIPS in its arbitrary distinction between pharmaceuticals utilising chemical entities and all other types of pharmaceuticals.

D. Article 39.3 TRIPS

a) Negotiation history

There is no official documentation of the negotiations of the TRIPS Agreement (as is the case for all other parts of the WTO Agreement). Although the Vienna Convention on the Laws of Treaties would allow such documents to be used as interpretive tools,¹³² the available documents, such as the various proposed versions of the text, are of no or limited use in clarifying the meaning of these terms and can hardly provide basis for legal arguments. Article 39.3, like many other parts of the TRIPS Agreement, has a number of vague or undefined terms. The available sources are only helpful to the extent that they provide some context and shed light on the intention of the negotiating parties.

Despite the US showing signs of some movement on the matter, the positions of the negotiating parties with regard to data protection can be expected to have remained largely the same since the introduction of TRIPS. The “North-South” divide has not changed significantly, the main centres of innovative and generic pharmaceutical industries are still largely located where they have been for the past decades. The EU and, to some extent even the US, can be reasonably expected to take a similar or even more extreme approach in promoting data protection in multilateral negotiations should such a negotiation occur today, whereas for example Brazil and India would be opposing it.

¹³¹ Nuno Pires de Carvalho, *The TRIPS regime of patent rights* (Kluwer Law International 2002) 276.

¹³² Article 32 VCLT.

As will be discussed later, in the synthesis of a multilateral standard for the data protection for biologics, one cannot take into consideration the legal principles and rationale underpinning data protection without also looking at the dynamics of negotiations. One must take into account how the most influential players have asserted their positions and what compromises they made, and how the parties arrived to the final text.

b) Standards

The TRIPS Agreement introduced the first internationally accepted standard of pharmaceutical data protection. Section 7 of TRIPS addresses the “Protection of Undisclosed Information” generally, a neutral term chosen instead of “trade secrets” or “confidential information” as it would appear in various jurisdictions.¹³³

Article 39.1 of TRIPS provides that:

In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.¹³⁴

Article 39.1 incorporates Art. 10bis of the Paris Convention into the section, which, together with Art 2.1 TRIPS, has the effect of imposing the obligations arising from Art. 10bis to all WTO Members. It also describes the protection of undisclosed information as being rooted in the protection against unfair competition.

Article 39.2 TRIPS describes the general obligation of Members to protect undisclosed information, and the conditions in which information shall be considered undisclosed:

Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices (10) so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.¹³⁵

Article 39.3 then goes on to describe a specific instance of this obligation, creating a right for innovators to be protected against unfair commercial use of certain test data:

¹³³ Daniel Gervais, *The TRIPS Agreement: drafting history and analysis* (4th edn, Sweet & Maxwell 2012) [2.486].

¹³⁴ Article 39.1 TRIPS.

¹³⁵ TRIPS art 39.2.

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.¹³⁶

The wording of this section has been the subject of vast amounts of analysis and interpretation as parties endeavour to find the meaning of the undefined or vague key phrases in the text. These interpretation exercises tend to follow certain paths as the parties attempt to substantiate their stance on IP and trade regulatory issues.¹³⁷ However, as neither WTO Panels nor the Appellate Body have been required to apply the clause, there is no authoritative interpretation of the text yet.

Undoubtedly, since its coming into force (for most WTO members on 1 January 2000), the implementation of TRIPS standards have resulted in elevated IP protection norms in most Members that adopted them. Article 39.3 has been designed to lay down a basic framework and to leave room for interpretation, allowing WTO Members to implement the provision according to their circumstances within their legal system and practice.¹³⁸

The text is now widely accepted by various commentators and policy-makers as an adequate and relatively low and flexible standard, particularly in view of the data exclusivity provisions negotiated in subsequent FTAs.¹³⁹ FTA negotiations are conducted behind closed doors, and it would be difficult to ascertain how the negotiators arrive at certain agreements, but it is likely that the common denominator articulated in TRIPS is used as an anchor point. In other words, the standard laid down in Art 39.3 is an internationally accepted baseline, or rather, an expression of a legal principle and rationale for the protection of certain clinical data.

The baseline standard articulated in Art 39.3 of TRIPS does not provide for a detailed regime of protection. In fact, having left some of the key terms undefined renders the provision flexible and open for interpretation by WTO Members. Despite countless attempts at reading specific requirements as to its implementation into the provision, leading scholars agree that Members have a wide range of options for achieving the prescribed standard.¹⁴⁰

Developed countries with high innovative manufacturing capacity, such as the US and EU regard this baseline a starting point, a minimum requirement, and trade negotiations offer opportunities for these countries to export their protection standards by requiring negotiating partners to apply particular methods of data protection, such as creating exclusive rights to data.¹⁴¹ IPRs make a valuable

¹³⁶ TRIPS art 39.3.

¹³⁷ Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* 60.

¹³⁸ TRIPS art 1.1.

¹³⁹ Daniel Gervais, 'International Intellectual Property's Institutional Problem' (*Kluwer Copyright Blog*, 2018 July 9) <<http://copyrightblog.kluweriplaw.com/2018/07/09/international-intellectual-property-s-institutional-problem/>> accessed 2019 June 19.

¹⁴⁰ Yu, 'Data Exclusivities and the Limits to TRIPS Harmonization' 31.

¹⁴¹ Grosse Ruse-Khan and others, 'Principles for intellectual property provisions in bilateral and regional agreements' 879.

bargaining chip, but it is difficult to determine with any precision what a particular data protection provision is worth.

Developing countries are in a better negotiating position if there is an accepted baseline against which a proposed FTA text can be measured. One of the functions of a multilateral standard is to serve the common interests of the entire international community. When a subset of the community negotiate a higher standard, they no longer pursue the overall goal of the community. They deviate from the standard, benefiting the party where the IPR holders reside, at the cost of the party that imports the products. I submit in this paper that a multilateral standard for the data protection of biologics, if ever negotiated, will likely be similar to Art. 39.3 of TRIPS, which is relatively low. This could benefit importer countries by serving as a contrast to the negotiated standard, leading to a higher and more accurately determined value afforded to the concession.

In the following paragraphs I will discuss the interpretation of the key terms relevant to data protection for biologics. In particular, I will look at the reason why Art 39.3 of TRIPS is not directly relevant to the data protection of biologics (“new chemical entities”), what kind of data is to be protected (“undisclosed”), and what are members expected to protect the data from (“unfair commercial use”). Next, I will turn to the relevance of trade secrets and unfair competition principles to data protection.

c) New chemical entities

Article 39.3 requires the protection of certain data relating to “products that utilize new chemical entities”. The key phrase for the purposes of this discussion is “chemical entities”, which is one of the many terms left undefined. The most pressing question for our purposes is whether the term excludes biologics.

On plain reading it does not apply to products utilising biologics. As unsurprising and innocuous as this statement might seem, in light of the emergence of post-TRIPS FTAs that apply the protection to pharmaceutical products generally, it raises some important questions.¹⁴²

The interpretation of WTO law is governed by the Dispute Settlement Understanding (DSU).¹⁴³ Article 3.2 of the DSU mandates the use of customary rules of treaty interpretation, which, in turn, have been read by WTO panels and the Appellate Body as a reference to Arts 31 and 32 VCLT.¹⁴⁴ Under these rules, the starting point is the ordinary meaning of the term,¹⁴⁵ which, in this case entails products synthesised and/or purified by chemical process. This is in contrast with products created by biological processes, predominantly mammalian cell cultures.¹⁴⁶ Chemical processes involve chemical and physical reactions, vastly different from biological processes. From a pharmaceutical perspective, the two types of products are most easily distinguished based on their manufacturing process.

¹⁴² For a relevant discussion see Hegedus-Gaspar, 'Data Exclusivity for Biological Pharmaceuticals: Is New Zealand in Breach of World Trade Organization Law?'.
¹⁴³ Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994), Marrakesh Agreement Establishing the World Trade Organization (1994), Annex 1C, 1869 UNTS 299.

¹⁴⁴ See WTO, *United States: Standards for Reformulated and Conventional Gasoline – Report of the Appellate Body* (20 May 1996) WT/DS2/AB/R.

¹⁴⁵ VCLT art 31.1.

¹⁴⁶ A. Kantardjieff and W. Zhou, 'Mammalian cell cultures for biologics manufacturing' (2014) 139 *Advances in biochemical engineering/biotechnology* 1.

There can be little doubt that the inclusion of the term “chemical” serves the purpose of restricting the scope of “products”. The principle of effectiveness in treaty interpretation would certainly require the treaty interpreter to give effect to all of the terms used in the text.¹⁴⁷ To extend the scope of the term to include biologics would diminish, if not extinguish, the term’s contribution to the meaning of the clause.

Further, biological and chemical entities existed as separate concepts and, in some jurisdictions, such as the US, were regulated separately at the time of the conclusion of the TRIPS. At that time the US only legislated for the data protection of chemical pharmaceuticals under the Hatch-Waxman Act since 1984. The BPCIA was not passed until 2009. It would not be reasonable to suggest that the negotiating parties intended to include biologics, despite the fact that they chose the term “chemical entities”.

However, it should be noted, that there is one example of the above-mentioned arbitrary and illogical definition of the term “chemical entities” that radically changes the plain meaning of the term “chemical entities” in an FTA. Article 20.29 of CETA uses this term, to which a footnote was attached to clarify its meaning “for greater certainty”.¹⁴⁸ According to the footnote, for the purposes of data protection, the “chemical entities” are to be taken to include biologics.¹⁴⁹ Article 31.4 VCLT allows special meanings to be given to terms in a treaty provided that it reflects the parties’ intentions. However, it does not follow that such an anomaly should affect other agreements.

In fact, subsequent practice of WTO Members points towards the conclusion that biological and chemical entities are separate concepts both legally and from the perspective of the pharmaceutical industry. The most obvious example of this is the US where the domestic regulations of the two types of pharmaceuticals are vastly different. The IP chapters of the latest US FTAs also contain separate headings with different requirements for biologics and chemicals. The plain meaning of “chemical entity” is not changed by the fact that other jurisdictions such as the EU are regulating data protection for the two types together or that the FTAs of the EU and EFTA states typically use the term “pharmaceutical” which includes both types.

d) Undisclosed

Undisclosed test or other data is undisclosed information, which is the term the WTO negotiators chose instead of “trade secret”.¹⁵⁰ The protection of trade secrets has been made mandatory by TRIPS, in the context of protection against unfair competition. Hence, the protection only applies to clinical test data that is undisclosed in terms of the conditions under Art 39.2 of TRIPS.

e) Unfair commercial use

Article 39.3 requires that Members protect undisclosed test data from “unfair commercial use” and from disclosure. These are two separate obligations, however there is a connection between them. Protection against unfair commercial use is mandatory, without exception. Disclosure, by contrast, may be allowed under one of two exceptions. First, disclosure may be necessary to protect the public; second, if there are measures in place that protect the formerly undisclosed information from unfair commercial use.

¹⁴⁷ The principle of effectiveness, *United States: Standards for Reformulated and Conventional Gasoline – Report of the Appellate Body* 12.

¹⁴⁸ CETA art 20.29 fn 30.

¹⁴⁹ Ibid.

¹⁵⁰ Gervais, *The TRIPS Agreement: drafting history and analysis* [2.486].

The overall effect is that undisclosed data that falls into the scope of the obligation must be protected against unfair commercial use while it is undisclosed as well as when it is disclosed by the Member where disclosure would not have been necessary to protect the public.

The term “unfair commercial use” is not defined in TRIPS and it has not been subject to interpretation by WTO adjudicatory bodies.¹⁵¹ There is a considerable amount written on the proper interpretation of this term. The analyses often focus on the questions whether “use” includes “reliance” or “indirect use” for the purposes of approving the same active ingredient in a different product,¹⁵² and what the concept of fairness entails in this context. In summary, the consensus of leading scholars in the field is that Art 39.3 of TRIPS has flexibilities that allow Members to implement the requirements in different ways. For example, the text allows a period of exclusivity, but one cannot read an objective minimum requirement into the provision. The concept of fairness should be understood in light of Art 39.1 and its reference to Art 10*bis* of the Paris Convention. The requirement is that Members apply the concept of fairness according to the relevant domestic standards. The international minimum standard for unfair competition is relatively low (“contrary to honest practices” in Article 10*bis*(2) of the Paris Convention), which a follow-on manufacturer is unlikely to breach by relying or attempting to rely on the safety and efficacy profile of the product of a previous market entrant.

The meaning of “unfair commercial use”, in the context of unfair competition, as per Art 39.1, gives rise to strong arguments against an exclusivity based interpretation, although there are valid arguments both ways.¹⁵³ As seen in many FTAs discussed below, “protection against unfair commercial use” may very well entail mandatory exclusive rights for a period of time. Shifting test data protection out of the realm of the unfair competition into its own category helps to disarm those who argue against data exclusivity on the basis of unfair competition rules. Then there is no need to argue that, for example, reliance on another manufacturer’s previously submitted test data or on its successful market authorisation, is contrary to honest commercial practices.

However, as per Art 39.3, the minimum standard of protection is low, much lower than the five to ten years of exclusivity as formulated in subsequent FTAs. This escalation in the level of protection may be alarming for those who advocate for better access to medicines in poorer regions. However, from a strictly legal perspective, as far as chemical drugs are concerned, it would be difficult to raise an issue, since TRIPS explicitly allows the introduction of more stringent protection.¹⁵⁴ Members are allowed to implement the high level international rules the way it suits them best, although within certain boundaries. Article 39.3 certainly can be interpreted as grounds for exclusive rights. As far as biologics are concerned there has not been an internationally accepted minimum standard laid down before, yet FTAs are already mandating exclusivity as a means of protection.

Medicine regulation is generally such that, although hypothetically possible, countries, in line with their obligation under Art. 4 TRIPS (MFN clause), typically avoid implementing parallel regulatory regimes for medicines originating in different countries. Consequently, if a country agrees to a particular regulatory protection, for example, a period of exclusivity, pursuant to an FTA, there will a

¹⁵¹ See TRIPS art 39 fn 10 in relation to “a manner contrary to honest commercial practices”.

¹⁵² See for example Correa, *Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement* 384 and Reichman, ‘The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?’ 142.

¹⁵³ See generally Shaikh, *Access to medicine versus test data exclusivity: safeguarding flexibilities under international law* 32 ff.

¹⁵⁴ TRIPS art 1.1.

single regime applying to all medicines across the board, regardless of origin. This means that countries that already accepted such terms in any one of the multitude of FTAs that they are party to have no incentive to agree to any lower standard in future negotiations. Should a multilateral negotiation occur on the subject of data protection for biologics, countries opposed to data exclusivity will have to offer some trade-off to have any prospect of success.

E. Data protection in FTAs

Analysing data protection provisions in current FTAs is relevant for our purposes for two distinct reasons. First, while there is no multilateral standard for the protection of clinical data relating to biologics, provisions to this effect are being included in an increasing number of bilateral and regional agreements. These can shed some light on the path a hypothetical multilateral negotiation may take or, at least, what might be the standards that the signatories of these FTAs may seek to establish. Although, it must be conceded that the chance of any progress in the current WTO negotiation round is virtually zero.¹⁵⁵ However, it is still worthwhile to appraise the current trends to inform the development of a hypothetical common ground.

It has been pointed out that, as far as the developed countries, particularly the US, are concerned, bilateral and regional FTAs are the preferred forum to establish ever increasing standards of IP protection.¹⁵⁶ Developed countries, where the innovative pharmaceutical industry generates significant wealth, have a strong incentive to export their high IP protection standards. FTAs solidify these higher standards and generally become the starting point of future negotiations.

The second reason is that, although the basis of pharmaceutical data protection has been formulated in TRIPS, FTAs that contain higher levels of protection, so called TRIPS-plus standards, have the potential to modify the global standard via the MFN¹⁵⁷ principle. Article 39.3 is useful as a model standard, being the only data protection provision accepted by the entire WTO community. However, the MFN clause in TRIPS lacks an economic integration exception, causing FTAs to have a ripple effect that affects countries beyond the signatories to the FTA, and potentially elevate the standard of protection globally.¹⁵⁸

If IP provisions are to be included in any future agreement, the starting point of the negotiations will be the highest standard found in any negotiating party. Of course, a party that subscribed to a particular level of data protection may still enter agreements that require a lower standard, but it will be the higher standard that sets the minimum requirements for that country.

In addition to the above points, analysing recent FTAs may shed light on the considerations and intentions of the negotiating parties relating to pharmaceutical data protection. Discerning the rationale behind IPRs can be helpful in the endeavour to envision an acceptable minimum standard. However, as regards many existing and proposed standards, particularly those affording a higher level of protection to test data relating to biologics, no rationale can be ascertained from the text.

¹⁵⁵ Simon Nicholas Lester, Bryan Mercurio and Arwel Davies, *World trade law: text, materials, and commentary* (Third edn, Hart Publishing, an imprint of Bloomsbury Publishing Plc 2018) 58.

¹⁵⁶ Ibid 869.

¹⁵⁷ TRIPS art 4.

¹⁵⁸ Grosse Ruse-Khan, 'Protecting Intellectual Property under BITs, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?' 495.

By contrast, the language of Art 39.3 of the TRIPS implies that data protection may be considered a reward for efforts invested in the generation of test data where it involved considerable effort.¹⁵⁹ This may also entail a proportionality test where the level of protection may depend on the size of the investment.¹⁶⁰ Further, the obligation of all WTO Members to protect test data from unfair commercial use suggests that there might be an uneven playing field and the purpose of the provision is to protect fair competition.

In many FTAs such clues as to the rationale or purpose of the provision are lacking, although some of them kept the “considerable effort” requirement and reference to “unfair commercial use”. Not spelling out the rationale of data protection provisions is problematic, particularly where a seemingly arbitrary distinction is made between chemicals and biologics in terms of data protection, such as the case under the now-abandoned US model.

Data protection provisions in many of the discussed FTAs follow a particular two-part structure. Typically, in the first part, the basic idea of data protection along the lines of Art 39.3 of TRIPS is recounted, often with modifications, for example to include biologics, or to extend the protection to information already disclosed, etc.¹⁶¹ A typical regulation would be the provision of an IPR, that is, a right to have a particular kind of information protected in the course of trade.

However, the typical provision then goes on, in the second part, to restrict the interpretation of the first part. Many of the discussed FTAs require a strict regulatory exclusivity period as the required method of implementation of the protection.

This leads to an anomalous situation. Firstly, as leading scholars have noted, the requirement of regulatory exclusivity goes against the traditional unfair competition principles which do not require monopoly rights.¹⁶² Secondly, IPRs traditionally belong to the jurisdiction of courts, an independent judiciary, rather than a market regulator, which is usually an agency of the executive branch of the government. Regulatory exclusivity places the arbitration of IPRs into the hands of a market regulator, which does not consider IP-related questions, such as determination of prior art or usefulness, in its decision whether to let a competitor onto the market. Thirdly, as a consequence, such market protection can interfere with the arbitration of other IPRs, such as patents. For example, if a market entrant is blocked by the marketing authority on the basis of data protection, it may compromise the would-be entrant’s ability to challenge a weak patent, because of the risk that even if the patent is successfully invalidated, the market exclusivity that relies on data protection, which is independent from the patent, may remain in place.

To conclude before moving on to the substantive discussion of current FTAs, data protection for biologics is a unique IPR (if one accepts it as such), in terms of its inclusion in trade deals. Although it is not uncommon for it to be regulated on the domestic level, its appearance and evolution on the international plane is remarkable in that a set of standards are emerging from a multitude of FTAs without recourse to a common denominator or a clear set of basic legal principles.

¹⁵⁹ Correa, *Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement* 375.

¹⁶⁰ Carvalho, *The TRIPS regime of patent rights* 276.

¹⁶¹ See, for example, Art 16.8.1 US – Singapore FTA and Art 18.9 US – Korea FTA.

¹⁶² Correa, *Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement* 382.

In the following sections I will discuss FTAs centred around the major proponents of data protection regulations in trade deals, with a view to identify trends and similarities that will inform a discussion on a hypothetical multilateral minimum standard.

1. US FTAs

Data protection provisions in trade agreements negotiated by the US typically require a five-year exclusivity period. Earlier versions show more similarity to Art 39.3 of TRIPS, for example in referring to “chemical entities”, applying the “considerable effort” threshold, and generally showing connection to the traditional trade secret protection.¹⁶³ A shift towards more comprehensive and restrictive standard can be observed in later FTAs, moving away from the TRIPS standard and extending the protection to biologics.¹⁶⁴

Some US FTAs follow the NAFTA model, which utilises a two-part structure.¹⁶⁵ This model typically grounds data protection in trade secrets. The basic rationale is that undisclosed clinical data required to be submitted to the market authority is to be protected against disclosure, particularly in light of the efforts required to gather such data. This sets the background for an IPR closely resembling Art 39.3 of TRIPS. The second part then goes on to specify how the protection is to be achieved. It typically mandates a five-year exclusivity or market protection.¹⁶⁶ Other US FTAs do not follow the two-part structure. Instead, these establish a strict regulatory exclusivity regime, without reference to any fundamental IP protection principles.¹⁶⁷

Based on the above observations, notwithstanding the risk of introducing an arbitrary distinction, one may attempt to draw a line between two broad types of data protection models applied in US FTAs, namely data protection regimes that apply the TRIPS model and those that do not. This distinction is useful in anticipating what model the US may support on the multilateral level.

From a theoretical perspective, the most significant difference between the two categories is their frames of reference. Regimes based on the TRIPS model can be appraised within a reasonably principled system that brought data protection under the trade secret regime, which is arguably part of the protection against unfair competition, as set out in Art 10*bis* of the Paris Convention.¹⁶⁸ In contrast, regimes not based on the TRIPS model are simple regulatory exclusivity regimes, with a questionable link to IP principles.

It is also noteworthy that there is no clear chronological tendency in the evolution of the data protection provisions negotiated by the US. The NAFTA model first introduced in 1994 was applied in the US-Panama FTA as recently as 2012. By contrast, introduced in 2003, the US-Singapore FTA provides for one of the most comprehensive exclusivity regimes.

In the following sections I will discuss the US FTAs separated into the above-mentioned categories. Due to the special circumstances surrounding the negotiations and subsequent amendments of the USMCA, I will consider this agreement under a separate heading.

¹⁶³ See NAFTA arts 1711.5 and 6.

¹⁶⁴ See USMCA art 20.48.

¹⁶⁵ See NAFTA arts 1711.5 and 6.

¹⁶⁶ See for example NAFTA Art 1711.6.

¹⁶⁷ See for example US-Singapore FTA art 16.8.1

¹⁶⁸ Carlos María Correa, *Research handbook on the protection of intellectual property under WTO rules* (Edward Elgar 2010) 718.

a) Regimes based on unfair competition law

The earliest formulation of a data exclusivity standard in an FTA can be found in Arts 1711.5 and 6 NAFTA. However, has now been superseded by the USMCA. Although NAFTA predates the TRIPS agreement, the US (and EU) were unsuccessful in their attempts to have some specific requirements incorporated into TRIPS. Thus, the NAFTA data exclusivity provision has additional layers of protection above what was eventually adopted under TRIPS, which is part of the reason why one may refer to the NAFTA provision as a “data exclusivity” provision as opposed to the TRIPS provision, which merely mandates the protection of certain clinical data, hence a “data protection” provision.

The original NAFTA provision, in its first part, similarly to the TRIPS, refers to chemical entities, includes the “considerable effort” requirement, and protects against “disclosure [...] unless steps are taken to ensure that the data is protected against unfair commercial use”.¹⁶⁹ This, together with the title of Art 1711 (“Trade Secrets”) indicate that pharmaceutical data protection under this regime is a special instance of traditional trade secrets.

According to Art 31(3)(c) of the VCLT, the preferred interpretation of an agreement is consistent with other treaties that the countries are also party to. The Appellate Body has considered Art 31(3)(c) of the VCLT as the articulation of the principle of systemic integration.¹⁷⁰

However, the second part of the data protection provision adds an extra layer onto the protection requirements relating to undisclosed information under TRIPS.¹⁷¹ It narrows the interpretive latitude of parties to specify what the protection shall entail. These requirements are far beyond those set out under the unfair competition principles and include protection against reliance on the data in support of a marketing application, and a minimum period of five years for such protection, effectively creating a minimum market protection period that reflects the US domestic standard set by the Hatch-Waxman Act.

This formulation was unprecedented and controversial at the time, setting the highest ever standard for data protection in a regional trade agreement. In the following decades, however, there have been significant variations in the drafting of FTAs. For example, the term “chemical entity” has been typically replaced by terms that encompass biologics as well, and the “considerable effort” requirement is often left out.

The question of what constitutes “reliance” on the clinical data has also proved to be problematic for the industry. The US Trade Representative used a different template for negotiations in some negotiations which reduces room for interpretation considerably, resulting in broader, highly restrictive and prescriptive data protection provisions.

There are a number of FTAs, such as the US-Colombia, US-Peru and US-Panama FTA, that model the data exclusivity regime on NAFTA provisions discussed above.¹⁷² These all follow the same two-part approach. However, a significant difference between NAFTA and these agreements is that the regime

¹⁶⁹ NAFTA art 1711.5.

¹⁷⁰ *EC and Certain Member States – Large Civil Aircraft* [845].

¹⁷¹ NAFTA article 1711.6.

¹⁷² US - Colombia Trade Promotion Agreement (11 November 2006, entered into force 15 May 2012); US - Peru Trade Promotion Agreement (signed 12 April 2006, entered into force 1 February 2009); US - Panama Trade Promotion Agreement (signed 28 June 2007, entered into force 31 October 2012); Shaikh, *Access to medicine versus test data exclusivity: safeguarding flexibilities under international law* 145.

comes under the title “Measures Related to Certain Regulated Products”, with no reference to trade secrets, other than the requirement that the submitted test data must be undisclosed.

b) Regulatory exclusivity regimes

The US-Singapore FTA, one of the earliest FTAs after NAFTA, was concluded in 2003. Its data exclusivity provision is one of the most comprehensive, with the widest scope and highest standard.¹⁷³ It does not follow the two-part model, as the fundamental TRIPS data protection provision is not repeated or referred to.

The regime comes under the title “Certain Regulated Products”, with no reference to trade secrets, explicit or implicit. Further, data to be eligible for protection need not be undisclosed. The requirements are not framed as protection of data, there is no reference to unfair competition or unfair commercial or other kind of use. Neither can one make any connection to the unfair competition framework that usually encompasses these regimes. The provision does not pretend to be an IP provision, but is framed in terms of regulatory exclusivity regime.

Further, importantly for our purposes, it refers to pharmaceutical products generally and does not restrict the scope of protection to chemicals. It sets up a sweeping data exclusivity for a period of five years, where the protection is extended to all data submitted for the purposes of marketing approval, and all products (i.e. not limited to new products or products of a particular kind, such as chemical or biologic).

Moreover, the provision extends to protection against marketing approval in a foreign territory. This additional measure has been part of the US Trade Representative’s template and is included in all of the more recent FTAs.

It also creates a patent linkage system, whereby a patent owner, usually the innovator drug company that first marketed the medicine, (1) must be notified if a follow-on manufacturer is seeking marketing approval, and (2) the regulatory authority must decline to approve a follow-on product before the expiry of the patent.¹⁷⁴

As will be discussed later, patent linkage does not provide effective protection for biologics. The applicability of such a regime to biologics would be problematic. In fact, the US has no patent linkage regulation in place for biologics. Consequently, it is unlikely that the US could reasonably expect its trading partners to have an effective patent linkage regime in place, given that it does not provide its own.

Article 17.10 of the US – Australia FTA is another example of a regime that does not follow the two-part approach.¹⁷⁵ There is no reference to the TRIPS agreement, and the mandatory market protection is not based on protection against disclosure, or a “considerable effort” requirement.

The provision refers to pharmaceutical products rather than chemicals only. As above, the wording of Art 17.10 is radically different from Art 39.3 TRIPS. As above, the data exclusivity regime established thereby displays no connection to trade secrets. Although the undisclosed nature of the information is still a condition, the provision is not part of a trade secret or undisclosed information regime. Instead, an elaborate regulatory exclusivity obligation is prescribed, including a prohibition of reliance

¹⁷³ US - Singapore Free Trade Agreement (signed 6 May 2003, entered into force 1 January 2004) art 16.8.1.

¹⁷⁴ Arts 16.8.4 (b) and (c).

¹⁷⁵ US - Australia Free Trade Agreement (signed 18 May 2004, entered into force 1 January 2005).

on foreign approval, extension for additional clinical information, and a further subclause to deal with protection against unfair commercial use in case undisclosed information is disclosed by a government agency. One of the effects of this subclause is that it equates the protection against “unfair commercial use” with the regulatory exclusivity regime prescribed, as far as the Parties to the agreement are concerned.

The meaning of “unfair commercial use” has been the subject of immense debate and the question is by no means settled amongst academics and negotiators.¹⁷⁶ By the same token, the question of what is an acceptable mechanism of protection against “unfair commercial use” is an equally controversial one.¹⁷⁷ Against this background, the parties to the US-Australia FTA agreed that data exclusivity is the preferred mechanism for protection against “unfair commercial use”.

By virtue of Art 4 TRIPS, any national of a WTO Member can claim the same treatment as prescribed under the FTA. Once the FTA is implemented in domestic legislation it is typically done in a non-discriminatory way, therefore it will automatically apply to all trading partners.¹⁷⁸ If countries formulate their understanding of the meaning of certain, otherwise undefined terms, in such clear terms, that can influence how the term will be interpreted later.

The US-Australia FTA also establishes an elaborate patent linkage system, where the market regulator is prohibited from approving a follow-on product, or a particular use of a product, if it is claimed in a patent. This ensures that no follow-on competition may commence until after all patent challenges are settled.

In addition, the data protection provision makes certain that the data exclusivity period may go beyond the expiry of the patent. This avoids another, often debated question in relation to these provisions, that is, whether data protection provisions can outlast the patent term of a pharmaceutical product. Again, even though the agreement settles the question vis-à-vis the signatories, the effect of this interpretation may spill over to other trading partners.

The DR-CAFTA brings together a handful of developing economies and the US. Similarly to the FTAs with Singapore and Australia, there is no reference to a TRIPS-like data protection principle.¹⁷⁹ The wording allows the inclusion of biologics in a regulatory data exclusivity regime. Article 15.10.1(a) prevents the market regulator to approve a follow-on product not only on the basis of the submitted data, but also on the fact of the approval. Therefore, under this regime the argument that a follow-on market entrant is not “using” or even “relying on” the innovator’s safety and efficacy data when it submits its application based on the fact that an identical product has previously been approved in the territory is moot.

Provisions of this kind establish an inflexible regulatory regime rather than providing for IPRs. The divorce from trade secrets, the supposed origin, is evidenced by the provision’s placement (under the title “Measures Related to Certain Regulated Products”) and the lack of certain terms associated with trade secret regimes, such as reference to Art. 39 of TRIPS.

¹⁷⁶ Shaikh, *Access to medicine versus test data exclusivity: safeguarding flexibilities under international law* 44 ff.

¹⁷⁷ Correa, *Research handbook on the protection of intellectual property under WTO rules* 718 ff.

¹⁷⁸ See, for example, Therapeutic Goods Act 1989 (Cth), s 25A.

¹⁷⁹ Dominican Republic-Central America Free Trade Agreement (signed 4 August 2004, entered into force 1 January 2005) (DR-CAFTA).

It is noteworthy that this format has been the preferred template for the US Trade Representative in later trade negotiations, as seen, for example, in Art 18.9 of the US – Korea FTA.¹⁸⁰ The requirements under this provision resemble those under DR-CAFTA, mandating a restrictive exclusivity regime, which also applies to biologics.¹⁸¹

Although the two-part approach has been discarded, the provision does utilise some terms that may have the effect of keeping the regime within the realm of traditional IPRs. The drafters chose to apply the “considerable effort” threshold instead of the “undisclosed” nature of the information concerned. Arguably, this allows some flexibility to exclude certain low-effort applications, depending on the government’s interpretation of “considerable effort”. However, this also results in the connection to trade secrets being completely severed.

Arguably, one may read an IP rationale into the “considerable effort” requirement, such that the five-year period of market exclusivity may be considered a reward for the effort invested in the origination of the clinical test data. As such, this provision is closer to an IP regime than those discussed above.

c) United States-Mexico-Canada Agreement (USMCA)

The USMCA was signed on 30th November 2018 by the negotiating parties, Mexico being the first to ratify it on 19th June 2019. However, following heated debate in Congress, the White House and the House Democrats agreed on a revised version of the agreement, and on 10th December 2019 all three negotiating parties agreed to the amended agreement.¹⁸² The final version of the agreement entered into force on 1st July 2020.

The United States Trade Representative (USTR), the government body in the US tasked with trade negotiations, prioritised IP protection and consistently advanced higher levels of data protection for pharmaceuticals.¹⁸³ Initially, it seemed to have managed to secure the longest term of data exclusivity for biologics ever included in an FTA. The USTR asserted that no legislative changes with regards to pharmaceutical IP protection will be necessary to implement the Agreement.¹⁸⁴ Nevertheless, many Members of Congress expressed their concern that even though the current level of protection need not be changed, the Agreement “would limit Congress’ ability to adjust the biologics exclusivity period”.¹⁸⁵ This objection was heeded by the White House and the data exclusivity provision was struck out of the revised version of the USMCA.¹⁸⁶

With the data protection provisions in the CPTPP being suspended, this leaves currently no FTA that envisages data exclusivity specifically for biologics. This is indicative of the highly controversial nature of these provisions. In fact, the rollback of the USMCA was not due to external pressure, but was

¹⁸⁰ Comprehensive and Progressive Agreement for Trans-Pacific Partnership (signed 8 March 2018, 30 December 2018).

¹⁸¹ See DR-CAFTA art 15.10.1.

¹⁸² USMCA Amendment Protocol.

¹⁸³ Office of the United States Trade Representative, 'Issue Areas: Intellectual Property' (*USTR Official website*, 2018) <<https://ustr.gov/issue-areas/intellectual-property>> accessed 12 July 2020.

¹⁸⁴ Office of the United States Trade Representative, 'Statement on USMCA and Drug Prices' (*USTR Official website*, 2019) <<https://ustr.gov/about-us/policy-offices/press-office/press-releases/2019/march/ustr-statement-usmca-and-drug-prices>> accessed 12 July 2020.

¹⁸⁵ *Letter from Representative Jan Schakowsky et al. to Robert E. Lighthizer, U.S. Trade Representative.*

¹⁸⁶ House Committee on Ways & Means, *Improvements to the USMCA* (Fact Sheet, 2019) <<https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/USMCA%20win%20factsheet%20.pdf>> accessed 12 July 2020.

initiated from within the US, with the majority of Democrats supporting the amendment.¹⁸⁷ The main argument against the ten-year data protection was concerns around high prescription prices in the US.¹⁸⁸ Notwithstanding this policy change, and keeping in mind the pressure exerted by pharmaceutical lobby groups on the USTR, it is not unreasonable to expect US foreign policy to revert to its previous stance on the question of data protection, in the foreseeable future.¹⁸⁹

(1) Data protection for biologics in the USMCA before amendment

In the modern history of trade negotiations, one of the major influencers of pharmaceutical data protection has been the US. Consequently, in attempting to map the trends of data protection for biologics, there is utility in taking stock of the formulation and requirements of the original data protection provision before the amendment to the USMCA was passed.

The data protection provision originally promoted by the US was the most comprehensive ever formulated.¹⁹⁰ The provision covered all pharmaceuticals, including biologics which had their own separate heading for further clarification of the specific requirements. This was a reflection of the US pharmaceutical market regulation, where chemicals and biologics have their own separate mechanisms, under the FDCA and the PHSA, respectively.¹⁹¹

The formulation aimed to close loopholes or shortcomings that came to light in a decade of patent litigation in the US and Canada.¹⁹² It called for the implementation of data protection so as to provide “effective market protection” for biologics, submitting that biologics need their own separate data protection regime. Pharmaceutical lobby groups, who have been vocal about the failure of patent law to secure appropriate market protection for biologics, would have welcomed the explicit wording.¹⁹³

Further, the term of “effective market protection” was to be set at ten years, double that of chemicals under the USMCA and all pharmaceuticals currently protected under previously concluded US FTAs. From the US’s perspective, the differentiation between the levels of protection for chemical drugs and biologics flows directly from the way the market is regulated domestically. However, aside from the TPP, this has never been reflected in an FTA before, and could have raised the question whether and how this differentiation may be justified, particularly in light of the EU and EFTA FTAs that typically deal with the issue of biologics by referring to pharmaceuticals in general. The attempt to introduce a separate provision for biologics however failed, and the question as to the theoretical basis of differentiation can be put aside for the time being.

In any event, it would have been difficult to ascertain the underlying rationale because the proposed model discarded the familiar two-part approach, moving significantly away from Art 39 of TRIPS. The

¹⁸⁷ Ibid.

¹⁸⁸ *Letter from Representative Jan Schakowsky et al. to Robert E. Lighthizer, U.S. Trade Representative.*

¹⁸⁹ Katrina Moberg, 'Private industry's impact on U.S. trade law and international intellectual property law: a study of post-TRIPS U.S. Bilateral Agreements and the capture of the USTR' (2014) 96 *Journal of the Patent and Trademark Office Society* 228 246.

¹⁹⁰ USMCA arts 20.48 and 49.

¹⁹¹ United States Federal Food, Drug, and Cosmetic Act of 1938, Pub L No 75-717, 52 Stat 1040 (FDCA).

¹⁹² Sanya Sukduang and Thomas J Sullivan, 'The Patent Dance' *European Biopharmaceutical Review* <<https://www.finnegan.com/en/insights/the-patent-dance-article.html>> accessed 28 May 2019.

¹⁹³ Biotechnology Innovation Organization (BIO), *BIO Statement on the United States-Mexico-Canada Agreement* (4 October 2018) <<https://www.bio.org/press-release/bio-statement-united-states-mexico-canada-agreement>> accessed 12 July 2020.

provision made no reference to unfair competition principles, and, indeed, offered no implicit or explicit rationale for the mandated protection.

The next section will deal with the definition of “new pharmaceutical product” applied in the agreement in more detail, however, there is one remarkable aspect of the original version worth noting. The parties chose to adopt a definition similar to earlier FTAs, where the definition contains a reference to “chemical entities”, which arguably makes it inapplicable to biologics. The drafters of the original version, in all likelihood, recognised this anomaly and included a footnote to clarify that, as far as biologics are concerned, it was not a requirement to extend the protection to second entrants.¹⁹⁴ This footnote, along with the section relating to biologics was deleted from the new version.¹⁹⁵

(2) Data protection for biologics in the USMCA

Even in its revised form, the provision kept some of the key characteristics that set it apart from previous formulae. It completely dispenses with the data protection rationale of Art 39 of TRIPS, directly setting up a regulatory exclusivity regime. The strict wording leaves little flexibility for implementation, while reinforcing the now well-established 5-year exclusivity requirement – rolling back the requirement in the original version which mandated an unprecedented 10 years of exclusivity for biologics.

Nevertheless, the wording ensures the coverage of biologics, and there also remains a number of other incremental changes that distinguish the USMCA from NAFTA. For example, the provision covers the issue of “reliance”, as seen, for example, in DR-CAFTA, i.e. marketing approval is not to be given either on the basis of information covered by the provision or on the fact of previous approval. It also covers products approved in another territory.

The provision, for the first time, refers to the marketing of a “similar” product, clarifying the term in a footnote. According to the agreement, similarity is made out if the marketing application of a follow-on product is based on test data or prior approval of another product.¹⁹⁶ It is an interesting twist on the concept of similarity, because the term is used by market regulators, such as the Federal Drug Administration (FDA) in the US or the European Medicines Evaluation Agency (EMA), in a clinical sense, in which case the determination whether two products are similar is based on clinical comparative analysis.¹⁹⁷ This may lead to a situation where two products are considered similar in terms of data protection even if the market regulator has not established similarity in the clinical sense.

The concept of “new pharmaceutical product” is defined under Art 20.49. As seen in some earlier FTAs, whenever the data exclusivity provision applies to “new” products, the parties adopt a broad definition of what amounts to a “new” pharmaceutical product, in an attempt to include pharmaceuticals that have not previously been marketed in the signatory country as opposed to globally.¹⁹⁸ Clearly, under the TRIPS data protection provision, the term “new” can be interpreted globally, so that a product marketed in any country would arguably no longer be a “new” product for the purposes of data protection in any other country. However, as the term is undefined under TRIPS,

¹⁹⁴ USMCA (pre-amendment) art 20.49 fn 45.

¹⁹⁵ USMCA Amendment Protocol, s 3E.

¹⁹⁶ USMCA art 20.48 fn 43.

¹⁹⁷ U.S. Food & Drug Administration (FDA), 'Biosimilar Development, Review, and Approval'; European Medicines Agency, 'Biosimilar medicines: Overview'.

¹⁹⁸ See for example DR-CAFTA art 15.10.1(c) and Australia-US FTA art 17.10.1(d).

WTO members are free to interpret it within reasonable bounds, and they are certainly free to adopt a particular interpretation under a FTA.¹⁹⁹

Interestingly, in various data protection provisions, the most often used wording is that a product is considered “new” if it “does not contain a chemical entity that has been previously approved” in the country.²⁰⁰ The reference to chemical entity raises the question whether a second entrant biologic could apply for data exclusivity, considering that it is unlikely to contain any chemical entities, thereby fulfilling the definition of “new” product. As mentioned above, the previous version of the provision attempted to deal with this anomaly by way of a footnote, which, however, did not make it into the amended version.

d) Conclusion

More than half of the FTAs discussed above use language that makes the data protection provision applicable to biologics. This is mostly achieved by omitting the reference to “chemical” products or entities,²⁰¹ and using a more general term such as “pharmaceutical” or “pharmaceutical product”. Some FTAs explicitly include biologics; the USMCA goes as far as restricting the marketing of “similar” products, securing the protection against biosimilar products.

The data protection provisions under all of these FTAs come under the IP chapters of the agreements, which indicates that these regimes are considered a method of IPR protection. However, the degree to which these FTAs depart from the TRIPS regime shows significant variance. Those discussed in the first section follow NAFTA model and tend to incorporate most of the original TRIPS flexibilities. Those discussed in the second section do not have as much in common with Art 39.3 of TRIPS. For example, the “considerable effort” threshold requirement may be absent, widening the scope of these protective regimes and potentially giving way to low-effort applications, or defining “new” pharmaceutical as one that is new to the particular territory.²⁰²

As a side note, one may observe that the definition of “new pharmaceutical products” keeps going back to the idea of “chemical entities”. That is, a typical definition section uses the following phrase “a new pharmaceutical product is one that does not contain a chemical entity that has been previously approved in the territory”. As mentioned above, biologics are typically not combined with chemical medicines, the logical result of which is that these products will always fall into the above definition of “new pharmaceutical product”, regardless of whether they are original or follow-on products. Further, since there is no international norm that would provide a fall-back definition of “newness” in this context, the interpretation and application of the provision may turn out to be a difficult problem.

In any case, these otherwise comprehensive data protection provisions do have common requirements. For example, they generally require a five-year exclusivity period where follow-on manufacturers are excluded from the market and prevented to apply for marketing approval. For those FTAs that do not follow the NAFTA two-part model, the prescribed regulatory exclusivity does not appear to be an enforcement mechanism of an IPR, but a simple regulatory regime without traditional rationale. Notably, however, the originally proposed requirement of “effective market

¹⁹⁹ Cf. TRIPS art 6 on exhaustion.

²⁰⁰ See for example US-Australia FTA art 17.10.1(d).

²⁰¹ Cf TRIPS Article 39.3.

²⁰² However, it is difficult to ascertain what amounts to “considerable effort” Shaikh, *Access to medicine versus test data exclusivity: safeguarding flexibilities under international law* 89.

protection” under the pre-amendment USMCA was eventually discarded, which can be taken as an indication that even the US was not prepared to take the level of protection to that extreme.

Typically in FTAs discussed in the second category, there is an overlapping five-year period during which foreign marketing approvals are also not allowed to be considered by the authorities. A patent linkage provision is also part of these *sui generis* regimes, which means that market authorisation can become directly dependent on the existence of a valid patent. This raises the barrier for a follow-on manufacturer that wishes to challenge an existing patent, for it does not matter how weak the patent or how good the prospect of success, it is not possible to bring the product to the market until the patent is defeated, which may take a long time and serious investment.

In effect, patent linkage provisions can be argued to bring the arbitration of IP law within the scope of the marketing authority. This further questions whether such data protection regimes can be properly labelled as IP protection, as they create regulatory exclusivities which affect areas of traditional IP laws, such as patents.

In recent trade negotiations the USTR promoted data protection provisions that showed a tendency to disconnect from traditional IP law principles, in which trade secret or undisclosed information regimes no longer appeared to serve as a framework. However, the amendment of the USMCA is indicative of the existence of a ceiling, which may have stopped the progression of this trend. It seems that, at least for the time being, the US is not prepared to push for more than five years of data protection, or to further facilitate the fundamental disconnect between the nominal purpose of data protection (protection of undisclosed information) and a prescribed outcome (market exclusivity).

The trend in shifting away from the concept of trade secrets has been desirable for the proponents of regulatory exclusivity as it allows to take data protection out of the wider context of unfair competition law. It has been argued ever since TRIPS has come into force that pharmaceutical test data must be protected in the context of protection against unfair competition.²⁰³ The meaning of “unfair competition” in treaty law has been laid out in Art 10*bis* of the Paris Convention, and it is not generally accepted to be applicable to the use of, or reliance on, pharmaceutical test data by follow-on manufacturers. Even if it is conceded that protection against unfair competition includes the protection of trade secrets, exclusive rights do not necessarily follow from that. In other words, data exclusivity is not mandated in the unfair competition context.

Consequently, divorcing the concept of pharmaceutical data protection from unfair competition law can help entrench the idea that effective data protection can only be achieved by exclusivity. Arguably, the US has a strong incentive, due to its innovative pharmaceutical industry, to mandate exclusive rights for new drugs. However, the direct attempt that has been made to create a *sui generis* regime that is unambiguous in that respect has caused serious concerns to the effect that medicine prices may spin out of control and the US eventually backtracked.

The relatively flat trajectory from NAFTA to the USMCA, the similarities between the different data protection provisions of the discussed US FTAs, along with the last-minute amendment of the USMCA and the failure of the TPP, show that, although there are examples of tight data protection requirements, the US and its trade partners seem to have come to a mutually acceptable standard of data protection, beyond which even the US is unwilling to go.

²⁰³ Correa, *Research handbook on the protection of intellectual property under WTO rules* 718.

With regards to biologics, this is a valuable piece of information; firstly, because it indicates the standard the involved countries might seek to establish (and what they will seek to avoid) on the international level; secondly, even if the members of these FTAs are not going to actively engage in multilateral negotiations, the mere existence of these data protection provisions influence the level of protection any country may be expected to grant to biologics.

According to the MFN principle as codified in Art 4 of TRIPS “any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members”. Although there are exceptions, these are not relevant in this context. Therefore, if, for example, the US grants a comprehensive five-year protection regime to test data relating to biologics originating from Canada and Mexico, then it is required to afford the same level of protection to all other WTO Members due to the lack of an economic integration exception clause as mentioned above. The same is true for all other parties to the FTA.

There is a significant number of countries that are now bound by these data protection provisions.²⁰⁴ As far as the signatories of these FTAs are concerned, the minimum standard of protection of test data relating to biologics is a minimum of five years of exclusivity, in many cases complemented by patent linkage. All these countries are now required to extend this protection to all other WTO members. This way, this type of data exclusivity, divorced from its origins, is multilateralised insofar as the signatory countries have seriously reduced their ability to lower the level of protection.²⁰⁵ Any agreements these countries may enter into in the future, can only ratchet the level of protection further up. Should a multilateral standard be proposed, anything less than a five-year exclusivity period, would be meaningless for these countries.

On the other hand, some of these countries have also agreed that pharmaceutical data protection is a separate regulatory regime that does not have a strong (if any) connection to trade secrets or to the protection against unfair competition, such as formulated under Art 39 of TRIPS. As for chemical entities, it has been very strongly argued that the TRIPS standard of data protection does not mandate exclusive rights.²⁰⁶

Therefore, it may be argued in case of biologics as well that separating the fundamental IP protection principles from the regulatory enforcement mechanism means that the required exclusivity does not flow directly from traditional trade secret or unfair competition laws. The regime is an independent enforcement regime with its own rules. Therefore, should a multilateral standard relating to data protection for biologics be negotiated, it could address the underlying principles and create a protection regime separately from the enforcement mechanism.

The NAFTA two-part model can already be interpreted this way, as the first part typically re-states the position taken by Art 39.3 of TRIPS. For those FTAs that do not follow the two-part structure, a multilateral standard may mandate data protection, without interfering with the regulatory regime adopted as a particular method of protection.

²⁰⁴ Australia, Bahrain, Canada, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea, Mexico, Morocco, Nicaragua, Oman and the US.

²⁰⁵ Grosse Ruse-Khan and Kur, 'Enough is Enough - The Notion of Binding Ceilings in International Intellectual Property Protection' 13.

²⁰⁶ Yu, 'Data Exclusivities and the Limits to TRIPS Harmonization' 31.

To conclude, it seems that the US abandoned its attempts at introducing a separate, higher-level requirement for the protection of undisclosed information in relation to biologics. Nevertheless, the wording of the relevant provision under the USMCA, along with its negotiation history, reveals a preference for a five-year of regulatory exclusivity, mandated independently from unfair competition principles.

<i>Table 1</i>	<i>Applies to biologics</i>	<i>Exclusivity period</i>		<i>Reliance on prior approval barred</i>	<i>Patent linkage</i>
		<i>Biologic</i>	<i>Chemical</i>		
<i>NAFTA</i>	No	-	5 years	No	No
<i>US-Peru</i>	No	-	5 years	No	No
<i>US-Colombia</i>	No	-	5 years	No	No
<i>US-Panama</i>	No	-	5 years	No	No
<i>US-Chile</i>	No	-	5 years	No	No
<i>US-Jordan</i>	No	-	-	No	Yes
<i>US-Singapore</i>	Yes	5 years	5 years	Yes	Yes
<i>US-Australia</i>	Yes	5 years	5 years	Yes	Yes
<i>DR-CAFTA</i>	Yes	5 years	5 years	Yes	Yes
<i>US-Bahrain</i>	Yes	5 years	5 years	Yes	Yes
<i>US-Korea</i>	Yes	5 years	5 years	Yes	Yes
<i>US-Morocco</i>	Yes	5 years	5 years	Yes	Yes
<i>US-Oman</i>	Yes	5 years	5 years	Yes	Yes
<i>USMCA</i>	Yes	5 years	5 years	Yes	Yes

2. EU FTAs

Data protection provisions in EU FTAs do not follow a particular format, but there are certain commonalities. For example, there is a consistency in treating pharmaceuticals as an all-encompassing group of therapeutic products, regardless of their origin or method of production. The EU approach suggests the adherence to an underlying principle to the effect that the IP in clinical test data should be protected in the same manner regardless of how the medicine was manufactured. This is a simple, straight forward principle that suggests that, since the manufacturing process is independent from the clinical trials, the protection of clinical test data should not depend on the nature of the medicine. Indeed, it is difficult to find a principled argument for singling out one subset of pharmaceuticals (e.g. biologics) and increasing the protection of test data relating to that subset only, even if it is done to counteract the perceived failings of patent protection.

Another relatively common element is either a reference to Art 39 TRIPS or the incorporation of a modified version of that text. Despite this connection, the standards under the EU FTAs tend to be higher than those under most US FTAs. The original TRIPS flexibilities appear to be modified or reduced to varying degrees.

Similarly to the section above, one may divide these EU FTAs into two broad categories, namely those that contain an explicit reference to Art 39 TRIPS, and those that do not. The relevance of this distinction is that it helps clarify the underlying principle on which the data protection provision rests, which then feeds into the discussion of what position the EU might take in terms of a multilateral standard.

Moreover, the analysis in this section further informs the discussion on the emergent nature of data protection in relation to biologics and reinforces the concern of spreading and ratcheting up the level of IP protection internationally. As countries shift from multilateral and regional agreements towards bilateral agreements, every country has an increasing number of agreements to reconcile, each with its own set of requirements. Data protection provisions typically require the existence of certain domestic market regulation that has little to do with trade. The authorities that regulate the pharmaceutical market are generally concerned with the safety of the population. Their role requires an unbiased approach toward the regulated products. Therefore, barring corruption, in terms of safety and efficacy it does not make sense to distinguish between products based on irrelevant factors, such as country of origin.

Consequently, each country typically has a single market regulatory system for all pharmaceuticals with little or no regard to their origin or manufacturing method, as long as the requisite manufacturing standards are met. Such a system must be compatible with the requirements of each FTA the country is signatory to. Since data protection provisions in the discussed FTAs set minimum requirements, it follows that each country will necessarily gravitate towards the highest standard.

In terms of negotiating multilateral minimum standards, the requirements established in the FTAs discussed here already set a minimum threshold for these countries. On the other hand, the existence of a multilateral provision that sets maximum standards may lead to conflicting obligations.²⁰⁷

a) Regimes referencing Art 39 TRIPS

There are only a handful of early FTAs that belong to this category. In more recent negotiations the EU seem to prefer to distance the data protection regime from TRIPS. A noteworthy exception is the EU-Vietnam FTA, an agreement not yet in force.

The first agreement negotiated by the EU that contains a data protection provision is the EU-Korea FTA.²⁰⁸ Article 10.36 brings the regime under the “Patents” subsection. No explicit reference to trade secrets or undisclosed information can be found. However, the provision refers to Art 39 of TRIPS to describe the kind of information the protection is extended to. Article 39 of TRIPS provides for the protection of undisclosed information generally, however as far as medicines are concerned, the protection is specifically applied to “undisclosed test or other data, the origination of which involves a considerable effort” relating to “chemical entities”.

²⁰⁷ For a thorough discussion of the "ceiling approach" in international IP law see Grosse Ruse-Khan and Kur, 'Enough is Enough - The Notion of Binding Ceilings in International Intellectual Property Protection'.

²⁰⁸ Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part [2011] OJ L127/6.

The provision requires that the prescribed protection is extended to data relating to pharmaceutical products, as defined under Annex 2-D of the FTA. Since that definition includes biologics, the intention seems to be that the scope of protection is not restricted to chemical entities, despite the direct reference to Art 39 of TRIPS.

Further, the level of protection required by the provision suggests that the reference to TRIPS was not made with the intention to allow flexibility in implementation associated with the unfair competition framework. Instead, it requires exclusive market protection for a minimum of five years.

Article 231 of the EU-Andean FTA refers directly to Art 39 TRIPS, bringing the data protection regime within its ambit and keeping most of the flexibilities associated with it.²⁰⁹ It keeps the original reference to “chemical entities”, further noting that for Peru and Ecuador the term of data exclusivity does not apply to biologics.²¹⁰ The same footnote states that, despite the reference to chemical entities, as far as Colombia is concerned, the exclusivity period will be extended to biologics.²¹¹

The EU-Vietnam FTA is one of the most recently negotiated trade deals and is not yet in force. The EU returned to a structure for data protection familiar from its Andean FTA. Article 12.41 of this FTA incorporates Art 39 of TRIPS and Art 10*bis* of the Paris Convention by reference and closely follows the wording of Art 39.3. It repeats most requirements, namely that the submitted data must be undisclosed and its assembly must require considerable effort. However, it goes on to prescribe a minimum of five-year protection period as the required method of implementation.

Further, the use of the word “pharmaceutical” and the addition of a minimum term of exclusivity significantly restricts the interpretive latitude available under TRIPS, extending the protection to biologics.

These FTAs follow a broadly similar pattern. Firstly, it sets out the IP principles with reference to Art 39 TRIPS, which would suggest that the regime is based on unfair competition law. However, instead of allowing the signatories to decide on the method of protection, the FTA prescribes a regulatory exclusivity regime for the purpose of implementation.

b) Regimes not directly referencing Art 39 TRIPS

Article 20.29 of CETA contains data protection as a separate IPR. The title (“Protection of undisclosed data related to pharmaceutical products”) suggests that the regime is a specific instance of a broader undisclosed information regime. Since both parties are also Members of the WTO, Art 39 of TRIPS may provide the framework for such a regime. Further, the formulation uses the terms also found in the TRIPS provision, bringing in the “considerable effort” requirement and the “protection against unfair commercial use”.

The structure of the provision has similarities to Arts 1711.5 and 6 of NAFTA in that it starts out by recreating much of Art 39.3 of TRIPS, followed by setting out restrictive requirements as to the implementation of the provision. Consequently, despite its connection to protection against unfair

²⁰⁹ Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part [2012] OJ L354/3; Protocol of Accession to the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part, to take account of the accession of Ecuador [2016] OJ L 356/3; The agreement has been in force between the EU, Peru and Colombia since 2013, with Ecuador joining in 2017; see also, European Commission, *Individual reports and info sheets on implementation of EU Free Trade Agreements* (Commission Staff Working Document, 14 October 2019) 41.

²¹⁰ Art 231 fn 80.

²¹¹ *Ibid.*

competition (as evidenced by its relationship to Art 39.3 of TRIPS), the prescribed market monopoly does not line up with unfair competition principles.

The provision refers to pharmaceutical products as well as chemical entities; however, a footnote purports to clarify that for the purposes of the provision the term includes biologics.²¹² The formulation of data protection is two-fold, similarly to the EU standards. It requires a minimum of six years exclusivity period, and an eight-year market exclusivity period, running concurrently. The effect of this is that at the end of the first six-year period a follow-on manufacturer may start the application process, to be ready for launch at the end of the eight-year market exclusivity period.

There is no protection against reliance on foreign authorisation. On the other hand, there is a prescribed *sui generis* regime under Art 20.27 which sets out an elaborate patent-term adjustment system to extend the period of a basic patent to make up for some of the lost time between the granting of the patent and the market authorisation.

Canada is also party to the USMCA. As discussed above, the original draft required a minimum of five years of data exclusivity for chemical drugs and ten years for biologics. Therefore, in order for Canada to fulfil its obligations towards both the US and EU it would have had to provide an eight-year market exclusivity for all pharmaceuticals with an additional two years of market protection for biologics. Canada currently provides six years of data exclusivity, during which no submissions for approval of follow-on products are allowed to be filed.²¹³ This is followed by an additional two-year period of market protection, during which applications may be submitted, but approvals may not be granted until the period ends. This applies to biologics and chemical drugs as well.

Another significant trading partner of the EU, Japan has a re-examination system for the purpose of protecting the public and ensuring the safety and efficacy of newly registered medicines.²¹⁴ The system does not distinguish between chemical and biological drugs. The law requires that a newly registered medicine be subjected to a post-marketing study. The period during which the study must be carried out is called the re-examination period. By law the re-examination period for a new medicine that utilises a new active ingredient (excluding orphan drugs) is eight years, during which generic or similar versions of the medicine cannot be approved for marketing unless a full clinical dossier is submitted to the authorities. The result is the same as in case of a data exclusivity provision: the effective prevention of market entry of follow-on products.

Article 14.37 of the EU-Japan FTA is titled “Treatment of test data in marketing approval procedure” and is brought under the subsection dealing with trade secrets. Since both countries have a relatively high level of market protection for original drugs, Art. 14.37.1 is not more than a brief description of the status quo, setting the minimum period of protection at six years. It clarifies the position that market protection applies to all pharmaceuticals, including biologics. It requires that the protection should prevent market entrants from both relying on and referring to the first entrant’s undisclosed test data.

²¹² CETA art 20.29.

²¹³ Food and Drug Regulations (CA), s C.08.004.1(3).

²¹⁴ Agreement between the European Union and Japan for an Economic Partnership [2018] OJ L 330/3 (EU-Japan FTA); Yoichi Okomura, 'Drug Re-Examination/Data Exclusivity in Japan and Neighboring Countries' (AIPPI Forum & ExCo Workshop Pharma IV, Helsinki, Helsinki, 6 September 2013).

There is, however, no mention of reliance on previous or foreign authorisation. This is likely due to the fact that both the EU and Japan have already measures in place to restrict market entrants in that regard.

Notably, the EU-Central America FTA stands out as a special case. Instead of providing for data protection directly, it contains a declaration to the effect that the EU agreed that undisclosed data will be protected via the MFN and NT principles.²¹⁵ In effect, the EU accepted a compromise as the current minimum requirements for Central American states under DR-CAFTA are lower than those under most EU FTAs.

The EU-Singapore FTA features a simple data protection provision, reminiscent of Art 39.3 of TRIPS, however, devoid of any qualification of the data (undisclosed or high-effort).²¹⁶ Article 10.33 sets a minimum exclusivity period of five years and applies to biologics by referring “pharmaceuticals” generally. Its placement under the “Patents” subsection is suggestive of a lack of connection to unfair competition principles and of an intention to create a regulatory monopoly by way of market exclusivity.

The EU-Georgia and EU-Ukraine FTAs, negotiated relatively recently, bring the most restrictive data protection provisions.²¹⁷ The regime is framed as for the purpose of protecting against unfair commercial use, an undefined term, familiar from Art 39.3 TRIPS. Protection against disclosure of, and reliance on, information submitted for obtaining marketing authorisation is extended to all submitted data. It is not a requirement that data be undisclosed or that a considerable effort be invested in obtaining it, and the provisions apply to biologics by virtue of the use of the broad term “medical products”.

Article 187(3) of the EU-Georgia FTA goes on to specify that the protection should be manifested in a six-year data exclusivity, with optional extension to seven years in case of a subsequent marketing authorisation for new indications. This signifies a regulatory exclusivity, without any meaningful connection to unfair competition principles.

An agreement in principle, the new EU-Mexico FTA is not yet in force at the time of writing.²¹⁸ The data protection provision is structured similarly to the NAFTA model, probably due to the fact that Mexico was party to the NAFTA at the time of the negotiations. Art X.50 is brought under Subsection 7 of the FTA, which deals with trade secrets.

However, the seemingly close relationship of the first subparagraph to the traditional unfair competition principles is eclipsed by the second subparagraph. Article X.50.1 lays out an IP protection provision, complete with the requirements of “considerable effort” and “protection against unfair

²¹⁵ “Declaration of the EU party on data protection of certain regulated products” Agreement establishing an Association between the European Union and its Member States, on the one hand, and Central America on the other [2012] OJ L346/3 2618.

²¹⁶ Free Trade Agreement between the European Union and the Republic of Singapore [2019] OJ L 294/3 (EU-Singapore FTA).

²¹⁷ Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part [2014] OJ L 261/4 (EU-Georgia FTA); Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part [2014] OJ L 161/3 (EU-Ukraine FTA).

²¹⁸ European Commission, 'New EU-Mexico agreement: The Agreement in Principle and its texts' (*EC Official News Archive*, 28 April 2018) <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1833>> accessed 22 July 2020.

commercial use”, familiar from Art 39.3 of TRIPS. On its own, this subparagraph would be a version of Art 39.3 that is somewhat clearer in its purpose. It is Art X.50.2 that overrides any possible flexibility in implementation, by prescribing a restrictive regulatory exclusivity regime to achieve the object of the first subparagraph.

The provision, entitled “Protection of undisclosed data related to pharmaceutical including biologics products” leaves no doubt that it is intended to apply to biologics. Indeed, unlike, for example, in CETA, much care has been taken to include biologics whenever pharmaceutical products are mentioned in the text.

The structure of the provision resembles Art 1711 of NAFTA, but with a more expansive wording, resulting in significant differences. The first section of the provision requires that the protection shall apply to a wider range of trial data, while the second section, following the NAFTA-layout, sets the minimum term of data exclusivity at six years.

Since Mexico is also signatory to the USMCA, its domestic market regulation will have to accommodate both agreements. Once all three of the USMCA countries implemented the above-mentioned FTAs, an interesting outcome will follow in which all three countries will offer a different period of market protection.

The EU is currently negotiating FTAs with Australia and New Zealand.²¹⁹ The IP chapters, as proposed by the EU, have been published for information purposes only as they have been tabled for discussion and are likely to change.

The tentative wording of the data protection provisions is identical in both FTAs. It features a new template that is more akin to the EU directive that established the current “8+2+1” system, than to any other provision discussed so far.²²⁰ Indeed, the provision in its current form aims to establish the same sui generis system, discussed above. However, the minimum exclusivity and protection periods are currently shown in square brackets, meaning that these have not been finalised yet and are likely to be subject to negotiation. The provision further clarifies that should both parties enter into another international agreement, that other agreement prevails in terms of the length of protection. Currently, there is no such other agreement.

Both Australia and New Zealand have been successfully protecting their pharmaceutical market, facilitating the early introduction of generic medicines to the market. Pursuant to the then commonly accepted interpretation of Art 39.3 of TRIPS, both countries amended their domestic laws and introduced a five-year data exclusivity period when TRIPS came into force. However, since that time both countries demonstrated consistent opposition to higher IP standards in relation to medicines. Consequently, it is likely that there will be strong opposition to the EU model of market protection as it would mean a significant change for both Australia and New Zealand.

The EU is obligated by Art 4 of TRIPS to offer the same level of protection to all WTO Members. This is a case in point of the above-mentioned multilateralization effect, whereby the higher IP standards are

²¹⁹ European Commission, 'EU-Australia Trade Agreement negotiations' (*EC Official News Archive*, 21 June 2018) <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1865>> accessed 22 July 2020; European Commission, 'EU-New Zealand Trade Agreement negotiations' (*EC Official News Archive*, 21 June 2018) <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1867>> accessed 22 July 2020; European Commission, 'Commission welcomes green light to start trade negotiations with Australia and New Zealand' (*EC Official News Archive*, 22 May 2018) <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1843>> accessed 13 July 2020.

²²⁰ Directive 2004/27/EC.

attempted to be “exported”, not necessarily because of industry lobby or government agenda, but by virtue of the MFN obligation embedded in TRIPS.

The other parties to the negotiations are obviously have the power to resist the EU proposal, resulting in lower standards of protection in the opposing parties. Should the EU agree to such a lower standard of protection, the agreement will not have any effect on its own regulatory system. It will only allow the other parties to the agreement to not reciprocate the higher level of protection offered to them by the EU.

c) Conclusion

The above-discussed agreements use robust language to include biologics in the purview of the data protection provisions. The EU’s own regulations do not distinguish between chemical and biologic drugs, and this is reflected in the FTAs, which typically use the word “pharmaceutical” or otherwise clarify the scope of the provision.

Another feature of these agreements is that, although the typical minimum standard of protection is at least five years of exclusivity, the title and the placement, along with the wording, suggests some connection to traditional trade secrets, although this varies significantly between the agreements. These texts often use terms, such as “confidentiality” and “non-disclosure”, which are reminiscent of Art 39 of TRIPS. However, in most cases the established regimes, particularly those discussed in the second section, are not based on unfair competition principles. Therefore, one has to look for the rationale elsewhere.

Notwithstanding, even if one accepted that the grounds for data protection is protection against unfair competition, the provisions leave little room for the parties to decide on their preferred method of implementation.

Parties to the above FTAs have accepted, as a minimum, five years of data exclusivity as a means of protecting the market against unfair competition. The formulation of the basic IPR shows a varying degree of distance from Art 39.3 of TRIPS. However, the original flexibilities or interpretation and implementation are mostly lost, with a marked increase in the minimum standard of protection.

In multilateral negotiations the starting point for these countries would be a data protection regime a minimum of five years of regulatory exclusivity for biologics. Notwithstanding the EU-Vietnam FTA, it is submitted that, in terms of data protection for biologics, the EU would find it advantageous and would likely support a multilateral standard that provided a basis for regulatory exclusivity regimes independent from unfair competition law.

<i>Table 2</i>	<i>Applies to biologics</i>	<i>Exclusivity period</i>		<i>Reliance on prior approval barred</i>	<i>Patent linkage</i>
		<i>Biologic</i>	<i>Chemical</i>		
<i>CETA</i>	Yes	8 years	8 years	No	No
<i>EU-Japan</i>	Yes	6 years	6 years	No	No
<i>EU-Mexico</i>	(Yes)	(6 years)	(6 years)	Yes	No
<i>EU-Korea</i>	Yes	5 years	5 years	No	No
<i>EU-Georgia</i>	Yes	6 years	6 years	No	No

<i>EU-Singapore</i>	Yes	5 years	5 years	No	No
<i>EU-Vietnam</i>	(Yes)	(5 years)	(5 years)	(No)	(No)
<i>EU-Australia</i>	(Yes)	(8+2+1)	(8+2+1)	(No)	(No)
<i>EU-New Zealand</i>	(Yes)	(8+2+1)	(8+2+1)	(No)	(No)

3. EFTA

The IP chapters of the EFTA trade agreements contain data protection provisions that closely follow a particular model that is similar in its structure to the EU model. Data protection in these agreements fall under the undisclosed information regime. Typically, in its first part the provision either includes by reference or, in case of contracting with countries that are not WTO Members, re-creates the TRIPS data protection provision, grounding the protection in the unfair competition framework. This is followed by the required method of implementation, which is typically a period of regulatory exclusivity regime.

The data protection provision under Art 4 of Annex XII to the EFTA-Hong Kong FTA incorporates Art 39.3 of TRIPS by reference in its first section.²²¹ The second section can be taken as the required method of implementation, a minimum exclusivity period of eight years. The protection is explicitly extended to biologics. The EFTA-Albania and the EFTA-Serbia FTAs repeats this, with the exception that biologics are not mentioned explicitly, instead they remain implicit in the word “pharmaceutical”.

The provision consists of two parts, the first part (as the title of the Article suggests) brings the regime under the unfair competition framework by reference to TRIPS. The second part prescribes the required method of implementation, taking away the flexibility of the signatories in that respect. Thus a period of regulatory exclusivity becomes the minimum standard.

EFTA–Ukraine FTA contains a data protection provision that also provides for additional protection for new indications.²²² The minimum requirement for protection is a minimum market exclusivity period, in this case for five years, with a concurrently running three-year period of data exclusivity, during which applications for marketing authorisation cannot be accepted. Section 7 explicitly requires that the level of protection shall increase should Ukraine enter into an agreement with a third party that requires a higher level of protection.

Montenegro, Bosnia and Herzegovina are not Members of the WTO, hence, any reference to TRIPS in their respective FTAs is omitted. Instead, the provision, in its first section, replicates Art 39.3 of TRIPS, with the inclusion of biologics. In the second part of the provision the implementation is prescribed, creating a regime that mirrors the EU standard 8+2+1 system. That is, a regulatory exclusivity regime comprising an eight-year term of data protection with an additional two years of market protection. One additional year may be secured by new therapeutic indications. The data protection provision under to the EFTA-Georgia FTA is similar, with the exception that the minimum term is six years, with

²²¹ EFTA-Hong Kong China Free Trade Agreement (signed 21 June 2011, entered into force 1 October 2012).

²²² EFTA-Ukraine Free Trade Agreement (signed 24 June 2010, entered into force 1 June 2012), annex XIII, art 5.

an additional one year for new therapeutic indications.²²³ The title of Art 6 and its wording suggest that the intention was to create an IP regime along the lines of traditional trade secrets.

Annex XIX of the EFTA-Central American States FTA contains a data protection provision that does not govern the issue of data protection “through a specific provision” of the agreement.²²⁴ Instead, it refers to the National Treatment and Most-Favoured-Nation principles, requiring that each nation provides the same level of protection to domestic and foreign applicants, and vis-à-vis foreign applicants.

It also states that by providing a protection period of five years to pharmaceutical products, a country satisfies its international obligations.²²⁵ Terms used in this section remain undefined and vague. For example, it is unclear whether “protection” refers to data protection or market protection or whether a pharmaceutical product needs to be new to be eligible for protection.

Despite not mandating any particular level of protection, the effect should not be underestimated. The MFN provision of the FTA has a ratcheting effect on the level of data protection in all parties. Article 6.1.3 of the FTA requires that each party grant “each other’s nationals treatment no less favourable than that accorded to nationals of *any other state*” (emphasis added). Therefore, should a party to the agreement enter into another agreement with any third country, agreeing to a higher level of protection, it immediately has to offer the same protection to all parties to the FTA.

The EFTA-Lebanon FTA has a single paragraph that nevertheless follows the two-part approach seen in many FTAs above.²²⁶ In the first sentence, the provision incorporates Art 39 of TRIPS, and sets the framework of data protection “in accordance” with the TRIPS provision. However, it then continues in the second sentence with a required method of implementation that leaves national lawmakers with two options. There must either be a minimum market exclusivity period of six years, or there must be “adequately” compensation afforded to the first market entrant. Arguably, this allows some regulatory flexibility in terms of a compensation scheme that would be more appropriate for a provision that, by reference to Art 39 of TRIPS, is part of the endeavour to protect the market against unfair competition. However, at the time of writing I found no evidence of the existence of an alternative compensation regime.

The EFTA-Egypt FTA contains a unique variant of data protection clauses. It incorporates Art 39 of TRIPS and restricts its interpretation, however, in a more flexible fashion than seen under other FTAs.²²⁷ It re-states and modifies the obligations of the relevant authorities. Under Art. 39.3 of TRIPS, the authorities may be allowed to disclose test data as long as it protects it from unfair commercial use. Under Article 3(e) this is no longer allowed, as the authority must “protect the data against disclosure and unfair commercial use” at the same time. However, the provision places a ceiling on the length of such protection. The authorities are required to protect the data until it is “no longer confidential”, or for a maximum of five years, whichever comes first. There is no requirement of non-reliance or other market protection measures. As a consequence, the question arises whether the

²²³ EFTA-Georgia Free Trade Agreement (signed 27 June 2016, entered into force 1 September 2017), annex XV, art 6.

²²⁴ EFTA-Central America Free Trade Agreement (signed on 24 June 2013, 19 August 2014), annex XIX, art 5(a).

²²⁵ Annex XIX art 5(c).

²²⁶ EFTA-Lebanon Free Trade Agreement (signed on 24 June 2004, entered into force 1 July 2007), annex V, art 4.

²²⁷ EFTA-Egypt Free Trade Agreement (signed on 27 January 2007, entered into force 1 August 2007), annex V, art 3(e).

modified obligations allow data exclusivity and market protection, such as the minimum of eight years required under, for example, the EFTA–Hong Kong FTA.

Five, ten or more years of data exclusivity and market protection seems to have been accepted as compliant implementation of the TRIPS data protection provision, in part, because there is no explicit mandatory ceiling. It is also the case that, as discussed above, the term “protection against unfair commercial use” has been interpreted to mean the exclusion of generic/biosimilar competition, and has been implemented as such in various jurisdictions. This is, in part, due to the inherent flexibility and vagueness of the terms, such as “use” and particularly “unfair commercial use”.

If it is accepted that the data protection provision under, for example, the EFTA-Hong Kong FTA, is compliant with Art. 39.3 of TRIPS, and it is implemented by an EFTA country, then it follows that according to this EFTA country the interpretation of “protection against unfair commercial use” is such that it mandates the exclusion of competitors from the market for eight years. In other words, this EFTA country protects data against unfair commercial use for a period of time, which exceeds five years, in contravention of Article 3(e) of Annex V of the EFTA-Egypt FTA. Consequently, it would appear that EFTA countries have taken on contradicting obligations arising from two (or more) different FTAs.

Notwithstanding, this data protection provision seems to be in keeping with Art 39.3 of TRIPS in terms of flexibility of implementation. While it mandates a term of protection, there is no obligation to implement the protection in any particular way, such as market protection or data exclusivity. This provision fits more comfortably into the unfair competition framework than the majority of the discussed data protection provisions.

A unique feature of the EFTA-Korea FTA provision is the introduction of the concept of adequate compensation for allowing a follow-on applicant to rely on the protected test data.²²⁸ There is no minimum requirement for the length of protection or exclusivity, therefore it is conceivable that if no other exclusive protection, such as a patent, is in place, follow-on manufacturers may request that the relevant authorities allow references to the protected undisclosed data submitted by the first applicant, immediately after the first approval was granted, provided that appropriate compensation is given to the first applicant. In the footnote to Art 3, however, it is stated that there is currently no such compensation regime.

In general, the EFTA FTAs follow the two-part approach to formulating data protection provisions. The first part incorporates or repeats Art 39.3 of TRIPS, which is the foundation of the provision. In this manner, these provisions are brought within the unfair competition framework under Art 10*bis* of the Paris Convention. This would suggest that data protection is intended to be framed as an IPR that requires protection. However, in the second part, the method of protection is typically prescribed for the signatories as a particular term of exclusivity.

Overall 17 countries have agreed in the above discussed FTAs to introduce a minimum exclusivity period of five years or more.²²⁹ Also, these FTAs typically use the word “pharmaceutical”, which

²²⁸ EFTA-Korea Free Trade Agreement (signed 15 December 2005, entered into force 1 September 2006), annex XIII, art 3.

²²⁹ Albania, Bosnia and Herzegovina, Chile, Costa Rica, Georgia, Guatemala, Hong Kong, Iceland, Lebanon, Lichtenstein, Montenegro, Norway, Panama, Serbia, Switzerland, Tunisia, Ukraine, with the exception of Egypt and Korea.

suggests the underlying idea that there should be no distinction between the levels of protection provided for test data relating to chemical and biologic drugs.

Prima facie, this suggests that any future negotiation of data protection concerning biologics will start from the agreed minimum standards. That said, a multilateral standard does not have to include a required method of implementation. In utilising the two-part model, all of the above countries accepted Art 39.3 of TRIPS as the source of data protection. It is only the second part that introduces a particular regulatory exclusivity as a way to implement the obligation arising from the first part. In a multilateral standard the second part does not have to be present.

<i>Table 3</i>	<i>Applies to biologics</i>	<i>Exclusivity period</i>		<i>Reliance on prior approval barred</i>	<i>Patent linkage</i>
		<i>Biologic</i>	<i>Chemical</i>		
<i>EFTA-Hong Kong</i>	Yes	8 years	8 years	No	No
<i>EFTA-Albania</i>	Yes	8 years	8 years	No	No
<i>EFTA-Serbia</i>	Yes	8 years	8 years	No	No
<i>EFTA-Ukraine</i>	Yes	5 years	5 years	No	No
<i>EFTA-Bosnia and Herzegovina</i>	Yes	8+2+1 years	8+2+1 years	No	No
<i>EFTA-Montenegro</i>	Yes	10 years	10 years	No	No
<i>EFTA-Georgia</i>	Yes	6 years	6 years	No	No
<i>EFTA-Tunisia</i>	Yes	5 years	5 years	No	No
<i>EFTA-Chile</i>	Yes	5 years	5 years	No	No
<i>EFTA-Central American States</i>	(Yes)	(5 years)	(5 years)	No	No
<i>EFTA-Lebanon</i>	Yes	6 years	6 years	No	No
<i>EFTA-Egypt</i>	Yes	(5 years)	(5 years)	No	No
<i>EFTA-Korea</i>	Yes	-	-	No	No

4. Comprehensive and Progressive Trans-Pacific Partnership Agreement (CPTPP)

As discussed in the introduction, the data exclusivity provisions under the CPTPP are currently suspended.²³⁰ However, it must be noted that the suspension may be reversed by mutual agreement of the contracting parties. Moreover, due to the striking similarities between the now-suspended data

²³⁰ CPTPP annex ss 7(e) and (f).

exclusivity provisions of the CPTPP and the now deleted provisions of the USMCA, and considering their similar fate, it is worthwhile to discuss these provisions in some detail.

The USMCA Amendment Protocol substantially changed the data protection provision in relation to biologics. With the most controversial sections omitted, the new version is more in line with the FTAs currently in force. However, for the purposes of this analysis, it is desirable to explore what regime the previous version of the agreement aimed to establish. If the suspension of the controversial TPP provisions was noteworthy, the revision of the USMCA is even more remarkable. The succession of these events strongly points to the possibility that there is a ceiling to the level of data protection that may be accepted in a trade agreement.

The text of the data protection provision under the CPTPP largely mirrors that under the pre-amendment version of the USMCA.²³¹ Articles 18.50 and 18.51 make no reference to the TRIPS data protection regime, or any other IP rationale for that matter. The two-part approach seems to have been abandoned. There is no first part that would lay the foundation for an IP regime or to link the provision to existing norms, such as Art 39.3 of TRIPS. The provision goes directly to what would belong to the second part in a two-part structure, that is, the method of implementation.

Despite the remarkable similarities, there is a significant difference with regards to biologics. Both agreements followed the same model in creating a separate provision to deal specifically with biologics, and prescribing a higher level of protection. However, the TPP negotiating partners successfully resisted the US push for twelve years of data exclusivity that was proposed initially. The end result was a choice between eight years of data exclusivity or five years of data exclusivity with additional market protection that “deliver a comparable outcome”. The provision leaves room for parties to determine what additional measures they choose to adopt. The expectation was that biologics require extra protection, which may go beyond the level afforded to traditional chemical pharmaceuticals in some countries.

While the differentiation between chemicals and biologics under the suspended provisions is not as marked as under the previous version of the USMCA, a differentiation was nevertheless made. This model was expected to be proposed in future negotiations, as the industry keeps stressing the importance and necessity of more comprehensive protection for biologics.²³² A signatory country, such as New Zealand, may choose to either keep regulating chemicals and biologics under the same legislation, thereby having to afford the same, higher level of protection to chemicals as well as biologics, or it may try to avoid unnecessary barriers to competition for chemicals by creating separate regulation for biologics, following US example. This approach might lead to a more complicated regulatory system, but more importantly, it could deepen the divide between biologic and chemical pharmaceuticals, thereby reinforcing the view that these pharmaceutical products have to be regulated separately.

Interestingly, whereas the US withdrew from the TPP, the revision of the USMCA concerning the unprecedented ten years of data protection for biologics was initiated by the US itself. Arguably, this may suggest an upper limit of data protection above which even the US is unwilling to go politically,

²³¹ CPTPP arts 18.50 and 51.

²³² The Pharma Letter, 'Why IP protections are important for biologic medicines' (*Biotechnology news*, 19 July 2019) <<https://www.thepharmaletter.com/article/why-ip-protections-are-important-for-biologic-medicines>> accessed 1 February 2020.

and that the international community perceives the US data protection model, separating biologics from chemical drugs, to be unsuitable for international trade regulations.

Indeed, there is a lack of principled legal reasoning as to the basis of such a distinction, particularly as the EU and EFTA models and almost all of the FTAs discussed above make no such distinction. Originally, the subject of data protection was clinical test data. When a medicine is trialled for safety and efficacy, the data is generated and processed for the purpose of supporting the therapeutic claims relating to the medicine. The nature of the gathered data is the same regardless of how a medicine is manufactured. The efforts involved in generating the data are also independent from the manufacturing process. Therefore, the EU approach seems more logical.

Contrariwise, data protection and market protection are two different concepts. One might argue that, in terms of data protection, distinctions should not be made between chemicals and biologics. However, a mechanism for market protection need not involve prohibiting reliance on data not generated by the applicant. Market protection can simply mean a given length of protection period. If different periods of market exclusivity are prescribed for chemicals and biologics, the regulation should not draw on (non-)reliance on clinical test data.

5. Conclusion

In the foregoing sections, I explored the data protection under FTAs currently in force (including those amended, proposed or under negotiation). The signatories to the above agreements represent the overwhelming majority of the world economy. It is clear that these countries have taken on certain obligations with regards to IP protection beyond the minimum requirements of TRIPS. Further, a consensus emerged amongst these countries to the effect that clinical data should be protected by way of an exclusivity regime and that it is desirable to extend such protection to clinical data relating to biologics.

F. Choice of fora

As seen above, data protection regimes vary considerably both on the domestic and international levels. In case of chemical drugs there the common ground established under TRIPS provides some context, and may be useful for purposes of interpretation. For countries that have not yet entered into regional or bilateral trade agreements that provide for data protection, a multilateral standard may serve as a baseline, in case an evaluation of a proposed legal instrument is called for. Such a standard helps negotiators appreciate the value of any particular requirement that reduces regulatory freedom. However, biologics lack an explicit common standard. The expected minimum level of data protection for biologics has not been formulated. This section will explore the available options for establishing an international minimum standard.

1. WIPO

The Paris Convention is administered by the WIPO and it is expected that any new type of IPR or subject matter brought under WIPO administration would be in line with existing treaties. Both Art. 39.3 of TRIPS and state practices (as evidenced by domestic regulations and trade agreements, discussed above) point toward the claim that test data protection is part of the endeavour to protect the market against unfair competition. Therefore, it is likely that if WIPO were to administer a treaty harmonising the protection of test data for pharmaceuticals, including biologics, it would be

compatible with IP principles expressed, for example, under Art 10*bis* of the Paris Convention. IP, as defined under the WIPO Convention, includes protection against unfair competition.²³³

WIPO is committed to facilitate international IP systems for the protection of “creations of the mind”.²³⁴ WIPO stands for IP that “can be defined as a set of principles and rules that discipline the acquisition, the use and the loss of rights and interests in differentiating intangible assets susceptible of being used in competition.”²³⁵ Even though clinical test data is information gained from observation rather than a creation of the mind, it may be argued that the resources and efforts invested in the creation of clinical test data could justify its protection. This would be in line with the emergence of traditional IP principles.²³⁶

The formulation of data protection as an IPR would have to recognise inherent value in the protected subject matter and would promote a system where the reward is commensurate with that inherent value. Traditional IPRs reflect the conflicting interests of the community, namely, to reward intellectual creation by forestalling counterfeiting and unfair commercial practices, on the one hand, and to promote access to knowledge and competition, on the other hand. In other words, to find the right balance between the costs and benefits associated with IPRs.²³⁷

It has been observed that the WTO was more desirable for developed countries, in terms of IP enforcement and outcomes than the WIPO, due to the latter’s one-state, one-vote rule and its focus greater on the interests of developing countries.²³⁸ At this juncture, it is worth noting that Art 71(2) of TRIPS in accordance with Art X(6) of the WTO Agreement allows the amendment of TRIPS “on the basis of a consensus proposal from the Council for TRIPS”, if the amendment is to increase the level of protection for an existing IP, and such is in force in another multilateral agreement. There is a case to be made that, if data protection is recognised by WIPO, there is a possibility for a TRIPS amendment.

In any case, the formulation of a *sui generis* IP in clinical data under the WIPO would likely be a balanced one that reflects the need to protect investment against counterfeiting and unfair business practices, while giving due consideration to the social costs of IP. This would inevitably lead to a flexible formulation, perhaps not unlike the one formulated under Art 39.3 of TRIPS.

Focussing on the IP subject matter, in this case clinical trial data, it is likely that WIPO would see no justification for arbitrarily narrowing the scope of protection to chemical drugs only. A data protection provision under WIPO would likely apply to all pharmaceuticals regardless of a manufacturing process.

As it stands, the WIPO has no specific mechanism to deal with the protection of clinical data, but it would arguably be in line with its ethos to mandate such protection on an “undisclosed information” basis, in accordance with its existing instruments, such as the Paris Convention.

²³³ WIPO Convention art 2(viii).

²³⁴ WIPO, 'What is Intellectual Property?' (*WIPO Official website*, 2019) <<https://www.wipo.int/about-ip/en/>> accessed 15th October 2019.

²³⁵ Nuno Pires de Carvalho, 'Test Data Protection - The WIPO Perspective' (Symposium on the Evolution of the Regulatory Framework of Test Data - From the Property of the Intellect to the Intellect of Property, Geneva, 8 February 2010) 3.

²³⁶ *Ibid.*

²³⁷ *Ibid* 34.

²³⁸ Susan K Sell, 'TRIPs Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP' (2011) 18(2) *J Intell Prop L* 447 450.

2. WTO TRIPS Agreement

The WTO framework offers the best and most commonly used enforcement mechanism in trade related issues.²³⁹ This was one of the reasons why IP protection was originally brought under the WTO.²⁴⁰

Article 64 of TRIPS refers to Art XXIII of the GATT, which prescribes how and on what grounds complaints may be brought under the WTO. It must be noted that the moratorium on non-violation complaints under Art 64.2 of TRIPS has been extended to 2020.²⁴¹ Currently only violation complaints can be brought before the WTO panel. Should the moratorium be lifted in the future, a lower threshold may suffice for a complaint.

Should a multilateral standard for data protection for biologics be negotiated and brought under TRIPS, it would become enforceable within the entire WTO community. For this reason, it is likely that such a standard will be heavily negotiated and carefully calculated so as not to give rise to a plethora of complaints. Therefore, while the WTO is a lucrative forum, it has its limitations exactly because of its wide membership and effective enforcement mechanism.

Article 39.3 of TRIPS is the only multilateral standard for the protection of undisclosed clinical data. The text is a result of a long and difficult negotiation process, requiring compromises from the opposing parties. The final formulation was a dramatic step at the time of the conclusion of the negotiations. However, since then there has been a rise of bilateral and regional agreements ratcheting the level of protection higher and higher.²⁴² Those agreements that regulate data protection are, for the most part, founded on the principles laid down in Art. 39.3 TRIPS. The provisions that utilise the two-part structure, as discussed above, typically contain a reference to the TRIPS provision in their first part. This is then followed by a second part that mandates a particular way of implementation, typically in the form of data or market exclusivity, or both.

It may be argued that, with regards to data protection as part of the unfair competition regime, a multilateral agreement should only mandate the protection of the market against unfair competition or unfair commercial activity, however, the method of implementation should be left to the individual members. This is certainly reflected in the current formulation of Art 39.3, which is silent on how to implement the required protection.

Further, in the above discussed FTAs that are based on the two-part model, one may observe the clear dividing line between the first part and the second part. The first part defines the basic IPR, which, in short, mandates the protection of a particular kind of clinical information against disclosure and unfair commercial use as part of the endeavour to protect the market against unfair competition. Insofar as undisclosed information, and unfair competition are accepted as IPRs, the first part references or restates this IPR.

²³⁹ This is mainly due to the authority of the Dispute Settlement Body to monitor the implementation of the rulings and recommendations in relation to disputes, and its power to authorise retaliation against a non-compliant Member, DSU art 2.

²⁴⁰ For a historical overview, see Peter Drahos, 'Global property rights in information: the story of TRIPS at the GATT' (1995) 13 *Prometheus* 6.

²⁴¹ General Council *TRIPS Non-Violation and Situation Complaints Moratorium* (adopted on 10 December 2019) WT/L/1080.

²⁴² Sell, 'TRIPs Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP' 448.

The second part, however, is where the regulatory exclusivity is typically prescribed for a period of five to ten years. On its own, such a regime could hardly be considered an IPR. It is merely a statement between the contracting parties as to their idea of protection against unfair competition. It may be argued that the enforcement mechanism chosen by a number of countries should not bear on the underlying legal principle. That is, a multilateral standard need not narrow down the regulatory freedom of the contracting parties. While the WTO may monitor the content of individual trade agreements via its competent bodies such as the Committee on Regional Trade Agreements, in general, Members are free to adopt higher standards than those required under a trade agreement.

The understanding of, and legislative protection afforded to, trade secrets or undisclosed information vary greatly among WTO Members. Broadly speaking, the requirements for protection of trade secrets or undisclosed information are that the information must be secret or undisclosed, it must have commercial value, and the right holder must make reasonable efforts to keep it secret.²⁴³ In the specific case of pharmaceutical products, the clinical data in question must also require considerable effort to originate.²⁴⁴

Although the scope of the provision is narrowed down to data relating to pharmaceuticals that utilise chemical entities, as opposed to, for example, biologics, the relevant tests and thresholds to be met for eligibility for protection relate only to characteristics of the information itself and the behaviour of the right holder. The origin and method of manufacture of the drug is only relevant so far as the scope of the provision is concerned.

In other words, the TRIPS model focuses on the clinical data, not the pharmaceutical substance. Therefore, it is reasonable to expect that a multilateral standard for the protection of clinical data relating to biologics would be formulated along the same lines as it has been for chemical drugs, since the characteristics of the pharmaceutical are irrelevant to the matter of protection.

It may be recalled, however, that the TRIPS model includes a “considerable effort” requirement, which may be interpreted as giving rise to a proportional reward system where the level of protection given to clinical data reflects the invested efforts.²⁴⁵ In this case it may be suggested that the efforts required to gather the clinical data when testing the safety and efficacy of biologics are greater as compared to traditional chemical drugs, therefore a higher level of protection is justified for biologics. However, the required efforts and costs to carry out clinical trials are largely independent from the characteristics of the tested medicine.²⁴⁶

Furthermore, one may consider the plain reading of the “considerable effort” requirement, in which case it is a simple threshold, the purpose of which is to allow Members to exclude certain submitted data from protection due to its “low effort” nature. For example, the US offers data exclusivity for line extensions for existing drugs, where the innovator submits clinical data to show safety and efficacy relating to a new therapeutic purpose.²⁴⁷ Other countries, such as New Zealand, which do not provide

²⁴³ TRIPS art 39.1.

²⁴⁴ TRIPS art 39.3

²⁴⁵ Carvalho, *The TRIPS regime of patent rights* 276.

²⁴⁶ U.S. Department of Health and Human Services, *Examination of Clinical Trial Costs and Barriers for Drug Development* (25 July 2014).

²⁴⁷ Drug Price Competition and Patent Term Restoration Act of 1984, Pub L No 98-417, 98 Stat 1585 21 USC 355(j)(D)(iv).

protection for line extensions, may argue that these additional submissions do not meet the threshold to be eligible for protection.

3. Bilateral and regional agreements

In the forgoing sections on the various FTAs, I outlined the current trend of promoting data protection regimes and other IP standards by way of trade deals. The US and EU have had considerable success in exporting their minimum standards leveraging their good bargaining position in bilateral negotiations. However, the failure of the US to do the same on a regional level is instructive.

One possible interpretation of the breakdown of the TPP negotiations, for example, is that in a plurilateral setting the US was unable to exert its dominance to a sufficient extent, or offer sufficient concessions, to have its preferred data protection regime accepted by the opposing parties. Alternatively, the US may have declined to continue the negotiations due to insufficient support from within the country. The turbulent journey of the USMCA towards ratification is certainly indicative of the lack of consensus within the US, particularly on the issue of data protection for biologics.

Notwithstanding the apparent loss of traction in the US, the EU continues in its endeavour to raise the minimum IP protection standards in its current trade negotiations.²⁴⁸ However, even if successful in its current efforts, it would be absurd to suggest that the EU, or any country, is capable of procuring world-wide consensus on data protection for biologics by way of bilateral trade deals.

Admittedly, the effect of Art 4 TRIPS (MFN clause) and the lack of an economic integration exception should not be discounted in this context. WTO Members raising their IP protection standards, for example, by implementing FTA obligations, must extend the same IP protection to every other WTO Member.²⁴⁹ This causes bilateral agreements to have an amplified impact that reaches beyond the immediate signatories.²⁵⁰ However, countries, whose nationals take advantage of higher level IP protection in another country, are not obliged to introduce similar regulations domestically. Thus the “globalisation” of such regulations in this way is not an inevitable outcome.

Consequently, bilateral and regional agreements can only have a limited “globalising” effect on data protection standards for biologics. It may be possible to observe the emergence of such standards in order to discover global trends, but the development of an enforceable multilateral standard should not be expected in this way.

G. Theory, rationale and legal principles behind data protection

Trying to ascertain the rationale behind data protection leads to complications. The first issue is that data protection, data exclusivity and market exclusivity are three different concepts that are often not used consistently in the literature. Second, the fundamental differences between these concepts are rooted in different rationales; yet, they are often conflated or confused, which leads to a mismatch between the regulation and its justification.

Legal texts in international agreements and domestic laws that create data protection, data or market exclusivity, do so with differing purposes and use a variety of definitions. Data protection is related to the concept of trade secrets or confidential information. It places certain limits on what a regulatory

²⁴⁸ European Commission, *Report on the protection and enforcement of intellectual property rights in third countries* (Commission Staff Working Document, 8 January 2020) 13.

²⁴⁹ TRIPS art 4.

²⁵⁰ Grosse Ruse-Khan and Kur, 'Enough is Enough - The Notion of Binding Ceilings in International Intellectual Property Protection' 13.

authority may do with the information submitted to it. For example, it may require the authority to keep the information confidential, or to protect it from being used by third parties.

Data exclusivity may be regarded as a specific instance of data protection, where the regulator is prevented from allowing third parties to use or refer to the information, which incidentally gives rise to an exclusive right. However, the first data protection regulation introduced by the US did not purport to have any connection with trade secrets, nor that its purpose was to keep clinical data confidential or, indeed, that the clinical data should be protected from anything other than being relied on by a follow-on applicant. The resulting exclusive right was not incidental to the purpose of the regulation, it *was* the purpose.

Data exclusivity creates market exclusivity for the relevant pharmaceutical, but it also restricts its use in other ways that raise barriers to follow-on manufacturers. Market exclusivity can be achieved without data exclusivity, for example, the seven-year market exclusivity period available under the Orphan Drug Act administered by the FDA to encourage research and investment in treatments for rare diseases.²⁵¹ Exclusive marketing rights, without reference to clinical data, were also made available for pharmaceutical products under the transitional arrangements in TRIPS.²⁵²

The most prominent formulation of a standard data protection provision is Art 39.3 of TRIPS. There is a clear expression of IP protection, that is, protection against unfair commercial use, given for investing in a medicine dossier. An innovator that wishes to enter the market, is required to disclose clinical information. However, the market authority must keep the data confidential and/or protect it from unfair commercial use. The rationale here, as alluded to above, can be understood in the context of unfair competition law (with reference to Article 10*bis* of the Paris Convention), which supports consumer protection by aiming at protecting the market as well as proprietary rights in certain information.²⁵³ Market authorities are prevented from facilitating unfair commercial practices to the detriment of the innovator that supplied the information. Incentivising innovation may be implied as an underlying rationale in the TRIPS formula of data protection. It may be amplified or tuned down depending on the particular implementation method chosen by each Member.

Another example is the Hatch-Waxman Act, which mandates a period of data exclusivity: it prohibits the marketing authority from approving a follow-on product via the abbreviated pathway whereby the follow-on applicant refers to the original product's previously approved clinical information instead of providing its own data. Since it is impracticable for a follow-on manufacturer to supply its own clinical information, the data exclusivity provision in this case creates *de facto* market exclusivity. Moreover, the sponsor of the original product may submit further clinical information supporting a new therapeutic purpose, which, if approved, may enjoy an additional term of exclusivity in respect of that particular change.

The purpose of this data exclusivity provision, in the context of the Hatch-Waxman Act which applies to traditional chemical pharmaceuticals, is not consumer protection. Proponents of the Act argued that data exclusivity is also not designed to simply protect proprietary rights in clinical data, but to find a balance between promoting price competition and creating incentives for innovation.²⁵⁴

²⁵¹Orphan Drug Act (1983) 21 CFR 316.

²⁵² TRIPS art 70.9.

²⁵³ See Paris Convention art 10*bis*(3)3.

²⁵⁴ Deloitte, 'Avoiding no man's land: potential unintended consequences of follow-on biologics' 6.

However, the validity of the claims of the pharmaceutical industry that data exclusivity is required to incentivise innovation is difficult to ascertain, as there is little available research on the topic.²⁵⁵ One may consider other types of exclusive rights, such as patents as models for examining the effect of monopoly rights on innovation. The existence of a positive effect in case of patents is by no means settled.²⁵⁶ What is certain, however, is that data exclusivity directly benefits the right holder and delays price competition. In summary, despite the supposed purpose of the Act, this type of data exclusivity can be best characterised as a means of protecting proprietary rights to clinical data.

However, it must be noted as an aside that other provisions of the Hatch-Waxman Act were successful in increasing price competition on the pharmaceutical market, such as the Abbreviated New Drug Application (ANDA) process, in light of which data exclusivity was arguably a necessary compromise.²⁵⁷

As for biologics, there is no multilateral data protection provision to set the standard. The US model, created by the BPCIA, provides a combination of data and market exclusivity.²⁵⁸ Once an innovative biologic is given marketing approval, no follow-on product will be considered by the marketing authority for four years.²⁵⁹ This initial period is a data exclusivity period, where the market monopoly is secured by an exclusive right to the use of the clinical data submitted to the market regulator. After four years follow-on applicants may submit applications to the authority, in which references to the first entrant's dossier are allowed. However, no application will be granted until twelve years after the first marketing approval. It is important to note that during the latter period the clinical data itself is no longer protected and the market monopoly no longer flows from the protection of the data. The product is simply granted a direct market exclusivity, which has no connection to the clinical data submitted to the authorities.

In this case, there is no indication of any consideration as to the value of data or the protection of consumers. Indeed, the market exclusivity mandated by the regulation has no relation to clinical data.²⁶⁰ The intention is to secure a given period of market exclusivity to incentivise innovation and investment in biologics, which is arguably unattainable by patenting.²⁶¹ Another function of the exclusivity period is that it serves as a counter-balance to the abbreviated licensure pathway (modelled on the above-mentioned ANDA) available for biosimilars under the BPCIA.²⁶²

It is commonly argued by the industry that, apart from incentivising pharmaceutical research and development, data exclusivity is desirable for a variety of other reasons as well, such as protecting

²⁵⁵ On how a myth becomes a policy consideration, see Anthea Roberts and Taylor St John, 'UNCITRAL and ISDS Reform: Plausible Folk Theories' (*International Economic Law and Policy Blog*, 13 February 2020) <<https://ielp.worldtradelaw.net/2020/02/uncitral-and-isds-reform-plausible-folk-theories.html>> accessed 17 July 2020.

²⁵⁶ Lisa Diependaele, Julian Cockbain and Sigrid Sterckx, 'Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity' (2017) 17 *Developing World Bioethics* 11 18.

²⁵⁷ 21 USC § 355(j).

²⁵⁸ 42 USC § 262(k)(7).

²⁵⁹ 42 USC § 262(k)(7)(B).

²⁶⁰ 42 USC § 262(k)(7)(A).

²⁶¹ See generally, Morgan, 'Regulation of innovation under follow-on biologics legislation: FDA exclusivity as an efficient incentive mechanism'.

²⁶² 42 USC § 262(k)(2)(A)(i)(I).

property rights in clinical data and to avoid the injustice of “free-riding” by follow-on manufacturers.²⁶³ Both of these claims are debatable, and do not provide a satisfactory rationale for data exclusivity.²⁶⁴

In terms of pharmaceutical innovation, the effect of data exclusivity, which is *de facto* market exclusivity, is very similar to the monopoly created by patents. Patents, however, require full public disclosure of the innovation in order for the innovator to be rewarded by the right to exclude competitors from the market. By contrast, data exclusivity does not require public disclosure of the clinical data. Furthermore, there is no reliable research currently available to show causation and correlation between data exclusivity and increased innovation.²⁶⁵

Patent linkage is an additional layer of protection which puts the onus on the competent authorities to keep the innovator company notified about potential follow-on entrants and provide protection against competition. Patent linkage creates a barrier against patent challenges, because the market regulator may refuse approval of a product based on a potential patent infringement. This strengthens patent protection which, in case of pharmaceuticals, is often weak to begin with, due to the difficulty of fulfilling the “inventive step” requirement.

Follow-on manufacturers may strategically enter the market before the expiry of the original drug’s patent at the risk of infringement. This often leads to pay-for-delay settlements, whereby the patent holder and the generic manufacturer settle the matter out of court, with the patent holder paying the would-be entrant for delaying market entry or challenging the patent.²⁶⁶ This practice has been criticised for being anticompetitive, and it highlights the problems surrounding pharmaceutical patents.²⁶⁷ Undoubtedly, notwithstanding patent linkage regulations, a follow-on manufacturer may still challenge the patent in question, if it is willing to invest in patent litigation without being able to enter the market or even to start the marketing approval process in the meantime.

It must be noted, however, that while patent linkage considerably increases the chances of staving off patent challenges for traditional chemical pharmaceuticals, it does not give a similar level of protection to biologics. This is because traditional pharmaceutical patents apply to a precisely described product, which cannot be circumvented. While these may be challenged on the basis of obviousness, the generic manufacturer cannot side-step the patent.

The US biologics industry found that their products generally cannot be protected the same way.²⁶⁸ Due to the complexity of biologics and the issues surrounding the patentability of biological substances,²⁶⁹ innovators file multiple patents to cover the product, often patenting the biological process rather than the end product.²⁷⁰ In the US, this led to drawn-out litigation between innovators and biosimilar manufacturers.

²⁶³ Diependaele, Cockbain and Sterckx, 'Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity' 16.

²⁶⁴ Ibid 20-1.

²⁶⁵ Diependaele, Cockbain and Sterckx, 'Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity' 18

²⁶⁶ Robin Feldman and Evan Frondorf, 'Drug Wars: A New Generation of Generic Pharmaceutical Delay' (2016) 53 Harvard Journal on Legislation 499 510.

²⁶⁷ Ibid.

²⁶⁸ Deloitte, 'Avoiding no man’s land: potential unintended consequences of follow-on biologics' 12

²⁶⁹ Morgan, 'Regulation of innovation under follow-on biologics legislation: FDA exclusivity as an efficient incentive mechanism' 101 fn 29.

²⁷⁰ Deloitte, 'Avoiding no man’s land: potential unintended consequences of follow-on biologics' 12.

Biologics in the US are approved under the PHSA. If successful, they are listed in the so called “Purple Book” maintained by the FDA. Unlike the “Orange Book” that lists chemical drugs, approved under the FDCA, the Purple Book does not list the patents linked with a particular biologic product. Hence, the US patent linkage system does not apply to biologics.

Instead the PHSA sets out a complex “patent dance” procedure to settle patent disputes.²⁷¹ It consists of rounds of disclosure and exchange of information, during which the patent-holder provides the follow-on applicant with a list of patents that would reasonably be infringed by the follow-on product; the follow-on applicant replies with its contention as to non-infringement, invalidity, etc.²⁷² There may be many rounds of such disclosure and information exchange. Then the follow-on manufacturer gives notice of its intention to market the product, after which the innovator patent-holder can still apply for an injunction.²⁷³

Biosimilar applicants may also choose not to engage in the patent dance procedure but start by providing notice of marketing and engage in patent litigation immediately. This is a riskier but shorter route for the follow-on manufacturer.²⁷⁴

The US example shows that patents are not very well suited to protect biologics and that extremely costly patent litigation is currently regarded as a necessary part of the development of new medicines. Arguably this cannot be alleviated, even by using the oft criticised patent linkage system, which does not necessarily contribute to the protection of biologics, for the same reason that patents do not afford the same protection to biologics as to chemical drugs.

H. The practical reality of negotiations

Legal principles and theory play a significant role in the development of multilateral norms, particularly in case of those representing fundamental values, such as the protection of human rights and the environment. It is largely accepted that the protection of IP is required for the fostering of creativity and facilitating research. In many ways, creativity and scientific research are means to improving the quality of life, placing IP protection high in the hierarchy of values.²⁷⁵ This is particularly important since IP protection has the potential to be abused by those favoured by it.

However, as the protection of IP has been brought into the arena of trade regulations, negotiation tactics, long-term strategies, international and national politics play a role just as important, if not more, as legal principles and theory. The negotiation history of international IP standards has shown that. Therefore, any attempt at synthesising a multilateral standard that has any chance of representing what might be agreed upon by the international community must include a number of practical considerations, such as the careful analysis of the negotiation history of similar standards, the past behaviour of key players, and present politics bearing on the topic.

The EU has shown an unwavering stance in promoting the inclusion of data exclusivity provisions in trade deals. However, the negotiation history of data exclusivity legislation within the EU reveals the

²⁷¹ For a brief overview see Sukduang and Sullivan, 'The Patent Dance'.

²⁷² 42 USC § 262 (2010).

²⁷³ Ibid.

²⁷⁴ Sukduang and Sullivan, 'The Patent Dance'.

²⁷⁵ See Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) art 27(2).

instrumental role of the pharmaceutical industry in its policy making.²⁷⁶ It has been argued that the EU pharmaceutical policy has been controlled by the industry through regulatory capture.²⁷⁷ This would indicate that the current EU approach may be predicated on the continuing influence exerted by the pharmaceutical industry. However, regardless of how the current rules came about, the result is that countries with generic manufacturing capacity and lower IP standards have a competitive advantage over the EU. Therefore, the existence of robust data exclusivity legislation provides a strong incentive for the EU to have its trading partners introduce similar rules.

That said, the influence of the pharmaceutical industry in trade negotiations is significant.²⁷⁸ The drafting process of the US proposals on the IP provisions of the TPP was secretive and tended to include only selected members of the affected industry.²⁷⁹ Many interested parties, such as, generic manufacturers, were not given proper opportunity to provide input. The overwhelming influence of the pharmaceutical industry on the drafting process resulted in US proposals that were unacceptable for other negotiating countries.²⁸⁰

This faulty, secretive process significantly contributed to the failure of the TPP negotiations as well as to the breakdown of the Anti-Counterfeiting Trade Agreement (ACTA). In the latter case the European Parliament refused to ratify the agreement partly because of the secrecy surrounding its negotiation.²⁸¹

Undoubtedly, negotiations are complex, and it is helpful if a level of confidentiality is maintained. However, it does not mean that key stakeholders should be left out of the process. If the US learned from the failures of the TPP and ACTA, it may be that in future negotiations a more open approach will be adopted, and feedback will be properly sought from all affected parties. Such an approach would lead to more balanced proposals, and greater support from different constituencies. It is noteworthy that, although not unexpected, the US withdrawal from the TPP was welcomed by many in the US.²⁸²

Similarly, the ratification of the USMCA met strong opposition in the US Congress. Despite the US having sufficiently high levels of IP protection so as not to require any adjustment, many members of Congress expressed their concern regarding the ratcheting effect of trade agreements. The main issue raised by the opposition was the diminishing policy space, a price the US may not be willing to pay for exporting its current standards of protection.²⁸³

²⁷⁶ See generally, Adamini and others, 'Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities'.

²⁷⁷ On the concept of regulatory capture, see Michael E. Levine and Jennifer L. Forrence, 'Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis' (1990) 6 *Journal of Law, Economics, & Organization* 167; Adamini and others, 'Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities' 995.

²⁷⁸ Diependaele, Cockbain and Sterckx, 'Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity' 14.

²⁷⁹ Moberg, 'Private industry's impact on U.S. trade law and international intellectual property law: a study of post-TRIPS U.S. Bilateral Agreements and the capture of the USTR' 246.

²⁸⁰ Sell, 'TRIPs Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP' 462 ff.

²⁸¹ Cooper Dreyfuss, 'Harmonization: Top Down, Bottom Up - and Now Sideways?' 360 ff.

²⁸² Joyce Frieden, 'Trump: U.S. Will Withdraw from TPP' (*Medpage Today*, 23 January 2017) <<https://www.medpagetoday.com/publichealthpolicy/healthpolicy/62691>> accessed 16 July 2020.

²⁸³ *Letter from Representative Jan Schakowsky et al. to Robert E. Lighthizer, U.S. Trade Representative.*

The USMCA is a significant trade agreement, and the US is rightly concerned about its limiting effect on the country's sovereignty. It would appear that even a developed country, with a strong research based pharmaceutical industry, has to balance the costs and benefits of IPRs. The US has shown its reluctance to support an international IP standard that is comparable to its domestic standard. In other words, a standard that is acceptable on the domestic level may be deemed too high for a plurilateral standard.

Further, opposition from countries like Brazil, India, and those from the African continent, would be guaranteed. The lack pharmaceutical data protection in these countries has drawn ample criticism from the USTR.²⁸⁴ The involvement of these countries in crucial developments such as the Doha Declaration on TRIPS and public health speaks to their strong commitment to keep affordable medicines on the market.²⁸⁵ Proposals to establish minimum data protection requirements for biologics should be expected to meet solid resistance from these countries.

The negotiation of Art 39.3 of TRIPS may be taken as a model. Admittedly, the minimum standards employed by developed countries have increased in the past decades, for example, the EU introduced the "8+2+1" system, and the BPCIA was enacted in the US. However, the stipulated minimum standards in trade negotiations seem to have levelled off, as evidenced by more recent bilateral and regional trade agreements.

The TRIPS text was a compromise between developed and developing countries. The middle ground was reached by accepting a level of protection that was regarded a maximum standard from the developing countries' perspective, but a minimum standard from the developed countries' perspective.²⁸⁶

Notwithstanding the accounts of questionable tactics employed during the negotiations of TRIPS Art 39.3, given the necessity of compromise, it is submitted that it is reasonable to expect a similar outcome, if a multilateral standard for biologics is ever to be negotiated.²⁸⁷

I. Synthesis of a multilateral standard for the protection of clinical data relating to biologics

The development of regional and bilateral trade agreements is, in a large part, due to the widely accepted view that the multilateral trade negotiations have stalled.²⁸⁸ This offers a plausible explanation as to why data protection provisions for biologics are included in FTAs while TRIPS remains unchanged. Undoubtedly, the push for higher levels of protection would achieve the inclusion of these provisions in FTAs even if there was an applicable TRIPS provision. However, in the current situation, where there is no common standard, these provisions showing "TRIPS plus" qualities have no reference point in TRIPS.

²⁸⁴ See, for example, Office of the General Counsel, 'Special 301 Report on Intellectual Property Protection and Review of Notorious Markets for Counterfeiting and Piracy' 50 and 78.

²⁸⁵ WTO, *Doha Declaration on the TRIPS Agreement and Public Health* (14 November 2001) WT/MIN(01)/DEC/W/2 (Doha Declaration).

²⁸⁶ Sell, 'TRIPS-plus free trade agreements and access to medicines' 58-59 and Acquah, 'Extending the limits of protection of pharmaceutical patents and data outside the EU - Is there a need to rebalance?' 267.

²⁸⁷ Gabriele Spina Ali, 'The 13th Round: Article 39(3) TRIPS and the struggle over "Unfair Commercial Use"' (2018) 21 *The Journal of World Intellectual Property* 201 206-8.

²⁸⁸ Lester, Mercurio and Davies, *World trade law: text, materials, and commentary* 334.

Currently, the only internationally accepted standard for data protection is Art 39.3 of TRIPS. As discussed above, it is formulated narrowly, so as to exclude biologics. The coverage of TRIPS, as stated in Art 1.2, is confined to those categories of IP that are explicitly referred to in that section. It was established by the Appellate Body that the coverage of TRIPS cannot be extended to new categories of IP.²⁸⁹ Thus, a compelling case can be made that IP in clinical data relating to biologics falls outside of TRIPS. Measures that purport to afford protection to such data by restricting trade in follow-on products could be regarded as barriers to trade, the elimination of which is a key principle of the WTO. Prior to the inclusion of TRIPS into WTO law IP protective measures were, in fact, regarded as barriers to trade, hence the explicit reference to traditional IPRs under the general exception clause.

Without an internationally accepted standard of protection and its inclusion in TRIPS, any IPR that directly or indirectly raises a trade barrier by creating a market monopoly and excluding competition may be challenged as inconsistent with WTO law.²⁹⁰ Yet, data protection in the form of data exclusivity for biologics has been granted in many developed countries for decades. This is an unfortunate disconnect between domestic and international norms.

It is likely that a multilateral standard that is acceptable for developing countries would be seen as affording too little protection for developed countries such as the EU and the US. It is unlikely, for example, that agreement could be reached as to a specific enforcement mechanism. This is part of the reason for developed countries' continuous attempts to gain ground via bilateral trade agreements. The difficulty in raising the level of protection or to mandate regulatory exclusivity as a mechanism of protection in larger scale is well illustrated by the failure of the TPP negotiations.

In bilateral and regional agreements pharmaceutical data protection provisions, like other IPRs, have been used as bargaining chips traded for market access or similar advantages.²⁹¹ It may be argued that the goal of trade deals, taken as a whole, is to have an exchange of concessions of equal value. However, this approach is not conducive to a balanced, mutually advantageous set of IP regulations.

By contrast, at the multilateral level, the goal has been to standardise IP protection across nations.²⁹² The harmonisation of IP regulation on the regional level, as an independent objective, has been part of a wider strategy to promote economic development in Europe and Asia.²⁹³ Trade concessions cannot play any significant role in the construction of functional international IP systems. Consequently, it is submitted that the result of multilateral negotiations is necessarily closer to a theoretical mutually acceptable, legally principled standard.

The multilateral standard has to be legally sound and balanced and it has to represent the common ground for a large number of countries. There can be no confusion between regulatory exclusivity and IP protection, such as seen in some of the FTAs discussed above, particularly those that attempt to

²⁸⁹ WTO, *United States: Section 211 Omnibus Appropriations Act of 1998 – Report of the Appellate Body* 1 February 2001 WT/DS176/AB/R [334]-[341].

²⁹⁰ For a more thorough discussion see Hegedus-Gaspar, 'Data Exclusivity for Biological Pharmaceuticals: Is New Zealand in Breach of World Trade Organization Law?'.

²⁹¹ Henning Grosse Ruse-Khan, 'Principles for intellectual property provisions in Bilateral and Regional Agreements' (2014) 36 *European Intellectual Property Review* 207 879.

²⁹² Grosse Ruse-Khan, 'Protecting Intellectual Property under BITs, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?' 5.

²⁹³ Michael Blakeney, 'The Role of Intellectual Property Law in Regional Commercial Unions in Europe and Asia' (1998) 16 *Prometheus* 341.

take data protection out of its unfair competition context and create a sui generis regulatory exclusivity regime without referring to data protection as an IPR.

Despite the significant efforts at shifting data protection away from the unfair competition framework, every data protection provision in the FTAs discussed above is posited as a form of IP. Further, in many cases the provisions retain certain terms, such as “undisclosed information”, “unfair commercial use” and “considerable effort”, suggesting that data protection still has its roots in a kind of IP that traditionally did not automatically confer exclusive rights. Exclusivity has certainly been one option. Yet, unfair competition regimes may also use compensation or cost sharing as alternative.²⁹⁴

Many WTO Members, including India, Brazil and others that generally oppose excessive IP protection for pharmaceuticals, would undoubtedly prefer a multilateral norm that does not mandate exclusivity, and would leave considerable room for implementation domestically. Article 39.3 of TRIPS is an obvious example where consensus was reached regarding the fundamental principles of data protection.

Given that the nature of clinical data which is the object of protective measures is the same regardless of the method of manufacture of the respective pharmaceutical, one might argue that the same protection that is afforded to clinical data relating to chemical drugs should be granted to data relating to biologicals. Consequently, a data protection provision for biologics based on the TRIPS model can be formulated by replacing the word “chemical” with “biological”, as follows:

Members, when requiring, as a condition of approving the marketing of pharmaceutical products which utilize **new biological entities**, the submission of **undisclosed** test or other data, the origination of which involves a **considerable effort**, shall protect such data against **unfair commercial use**. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against **unfair commercial use**.

Alternatively, Art 39.3 itself could be amended replacing the term “chemical entities” with “active moiety” or “active substance”.²⁹⁵ This formulation would suitably reflect the EU existing legislation and the data protection provisions included in the EU and EFTA FTAs. However, it would not sit well with the US approach to data protection where chemicals and biologicals are regulated under entirely different regimes.

Until very recently, the US had been promoting a different model that reflects its domestic regulation better. It seemed reasonable to suggest that the US would continue to encourage the formulation of a provision that applies to biologics only and would mandate their protection independently from existing protection afforded to chemicals. Setting aside, for the moment, the fact that the US has not succeeded in concluding these agreements in their original version, based on the negotiations and

²⁹⁴ J. H. Reichman, 'Legal Hybrids between the Patent and Copyright Paradigms' (1994) 94 Columbia Law Review 2432; Sanjuan Rius, Love and Weissman, 'The Protection of Pharmaceutical Test Data: A Policy Proposal'.

²⁹⁵ These terms are used in the US and EU law respectively to designate the part or ingredient in a pharmaceutical that is responsible for the physiological/pharmacological effect of the medicine.

previous versions of USMCA and TPP data protection provisions, it is submitted that the following formulation might be pursued by the US:²⁹⁶

If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, that is or contains a biologic, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall provide effective market protection, by not permitting third persons, without the consent of the person that previously submitted such information, to market the same or a similar product on the basis of (1) that information or (2) the marketing approval granted to the person that submitted such information, **for a period of x years** from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

The above formulation specifies the requirement for market protection based on the protection of undisclosed clinical data, for a period of time. However, it is likely that developing countries will not agree to a minimum protection period. Indeed, this wording is far more specific than Art 39.3 of TRIPS and would certainly draw opposition and criticism from developing countries. If a specific minimum period cannot be agreed on, it is submitted that it would be sufficient for the text to refer to a “reasonable period” instead.

Indeed, there is a case to be made for this approach, namely, in case of biologics it is useful to spell out the requirement for “effective market protection” due to the nature of the relationship between the original biologic and the follow-on products. As discussed above, biosimilars are not exact copies of the original product, which may allow the follow-on products to avoid patent infringement. In the same vein, the standard data protection provision that has been applied to chemicals, where the follow-on product is the exact copy of the original, may not provide sufficient protection for biologics, unless the desired outcome is made explicit.

Furthermore, it has been argued that a regulatory market exclusivity provides a better, simpler and more effective incentive mechanism than patents.²⁹⁷ The case is compelling as far as the US market is concerned, particularly considering the complicated patent system and the amount of litigation that occurs constantly. Developing countries may see some benefit in establishing a market exclusivity system that is simpler, more predictable than patenting biological entities.

Another issue with the above proposal is the use of the term “similar”. This term would have to be defined or clarified, as seen, for example, under the USMCA.²⁹⁸ Similarity in this context refers to the relationship between a follow-on product and its chosen reference product, the safety and efficacy data of which is referred to in the follow-on product’s dossier. To avoid confusion, the drafters would have to take into account the use of this term in the regulatory context, where a marketing authority approves a follow-on product as being similar to a reference product, in terms of safety and efficacy, in a therapeutic sense.

Comparing the above provisions, the success of the latter, more explicitly worded version seems less likely in a multilateral setting. The first version is analogous to an existing common standard, while the

²⁹⁶ Although it must be noted that the biologics data protection provisions were rolled back by the US itself, which may indicate that the US trade representative will no longer pursue this model.

²⁹⁷ Morgan – Regulation of innovation.

²⁹⁸ USMCA art 20.48 fn 43.

latter version is based on the US FTA template. Further, the majority of FTAs discussed above use wording akin to the TRIPS provision, and it is only a handful of FTAs that explicitly prescribe market exclusivity, suggesting that the concept may well be unacceptable for the wider international community. Further, there are no agreements in force that utilise the US model.

It is submitted, therefore, that in the unlikely event that a multilateral agreement be reached on the matter of data protection for biologics, a provision analogous to the current version of Art 39.3 of TRIPS has a better chance of success than one with a more explicit wording, mandating market exclusivity.

J. The utility of a multilateral standard

Undoubtedly, many would oppose it, but there would be some obvious benefits of a data protection standard for biologics included in, for example, TRIPS, alongside the standard for chemical drugs. Most likely, the main arguments against it would be similar to the objections raised in connection with data protection in general, i.e. its effect on access to affordable medicines, the delay it may cause for follow-on entry and price competition.²⁹⁹

However, the benefits of a harmonised IP system should not be underestimated. The proliferation of FTAs that contain varying data exclusivity provisions for biologics is not conducive to a principled outcome. A multilateral standard could provide common ground for negotiating parties and more predictability and certainty in the pharmaceutical market.

Furthermore, potential complications may result from the fact that the current IP framework does not provide satisfactory guidance as to the appropriate level of protection. For instance, if a WTO Member implements in its domestic regulation a high standard of IP protection for any reason, another Member may bring a complaint against that Member for delaying market entry for biosimilars.

Admittedly, the current threshold is quite high for IP-related complaints. First, non-violation complaints are currently not available under TRIPS.³⁰⁰ A case would be very unlikely to succeed as long as the moratorium is in place. Second, Art 1 of TRIPS explicitly allows the adoption of higher level of protection than required by the agreement. However, it is uncertain whether this applies to data protection for biologics, since this is not covered by Art 39.3 or any other TRIPS provision.

Many of the countries discussed above have chosen to implement the data protection obligation under Art 39.3 of TRIPS by way of a regulatory exclusivity regime. Insofar as Art 39.3 mandates the protection of clinical data for chemical entities, it provides the legal basis of an exclusivity regime the object of which is to ensure that protection. However, this mandate does not exist in relation to biologics, unless a different or new provision, such as proposed above, is adopted.

I have previously argued that, in principle, enforcement measures of IPRs that are not provided for in TRIPS may be challenged as violating WTO law.³⁰¹ Lacking an internationally accepted standard of data protection for biologics, a particular level of protection instituted by one Member may be perceived as a trade barrier by another.

²⁹⁹ See generally Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* 262-73.

³⁰⁰ *TRIPS Non-Violation and Situation Complaints Moratorium*.

³⁰¹ Hegedus-Gaspar, 'Data Exclusivity for Biological Pharmaceuticals: Is New Zealand in Breach of World Trade Organization Law?'

In a thought experiment, one may develop the arguments on both the complainant's and the respondent's side. In order to demonstrate the desirability of an internationally accepted standard for the protection of clinical data relating to biologics, the following section will present the arguments first within the existing framework, next in the hypothetical case where a multilateral standard, as proposed in the previous section, exists.

In this imaginary case, a Member may take issue with not being allowed to place its biosimilar product on a trading partner's market due to an existing data exclusivity regulation. The complainant may cite, for example, Art XI.1 GATT that requires the elimination of trade-restricting measures. The Appellate Body in *China – Raw materials* endorsed the interpretation of Art XI.1 given by previous panels that it applies to measures that have "a limiting effect on the quantity or amount of a product being imported or exported."³⁰² Data exclusivity legislation will prevent the marketing authority to approve a biosimilar product, making its sale illegal in the respective country.³⁰³

The respondent, having no directly applicable provision under TRIPS to justify the measure, may cite Art XX(d) GATT, which allows Members to maintain measures that are necessary to secure compliance with GATT-compliant laws and regulations. In essence, the respondent may claim that the data exclusivity is a GATT-compliant regulation and the delay in market entry is a result of necessary enforcement measure. Based on the jurisprudence of Art XX(d), in order for this defence to succeed, the onus is on the respondent to show that its requirements are met.³⁰⁴

First, the data exclusivity regulation must be GATT-compliant. Second, the marketing restriction must be necessary to secure compliance with data exclusivity. Third, the data exclusivity regulation must meet the requirements of the chapeau of Art XX. Supposing that data exclusivity does fall within the non-exhaustive list of regulations under Art XX(d), the measure secures compliance with the regulation, and the conditions of the chapeau are satisfied, the respondent has to establish that the enforcement measure is "necessary" within the meaning of Art XX(d).

The Appellate Body in *China – Publications and Audiovisual Products* explained the holistic "weighing and balancing" approach to the determination whether a particular measure is necessary for the purposes of Art XX(d) and whether there are any alternative measures available.³⁰⁵ There are at least four factors to be taken into account, namely, the offending measure's contribution to the enforcement of the regulation, "the relative importance of the common interests or values that the law or regulation to be enforced is intended to protect", the measure's restrictive effect on trade, and the availability of alternative options.³⁰⁶

³⁰² WTO, *China: Measures Related to the Exportation of Various Raw Materials – Appellate Body Report* (30 January 2012) WT/DS394, 395 & 398/AB/R [320] (*China – Raw Materials*).

³⁰³ See, for example, 21 USC § 331 in conjunction with § 355; Medicines Act 1981 (NZ), s 20 in conjunction with s 23B.

³⁰⁴ WTO, *Thailand: Customs and Fiscal Measures on Cigarettes from the Philippines – Report of the Appellate Body* (15 July 2011) WT/DS371/AB/R [177].

³⁰⁵ WTO, *China: Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products – Appellate Body Report* (21 December 2009) WT/DS363/AB/R [239]-[242] (*China – Publications and Audiovisual Products*).

³⁰⁶ The complainant may suggest alternative measures, which the respondent can then reject (for example, the alternatives are too costly, not technically feasible, etc), shifting the burden of proof; WTO, *Korea: Measures Affecting Imports of Fresh, Chilled and Frozen Beef – Report of the Appellate Body* (11 December 2000) WT/DS161 & 169/AB/R [162]-[163] (*Korea – Beef*).

One of the key considerations in this analysis is the balance between the second and the third factor. The Appellate Body explained in *Korea – Beef* that there is a correlation between the importance of interests and values at stake and the determination of necessity: the more important the protected interests and values are, the easier it is to accept the measure as necessary.³⁰⁷ Further, trade restrictiveness in this case can be measured by the length of the exclusivity period.

It is submitted that this potentially leads to an absurd outcome, because in the final analysis of the “weighing and balancing” approach the adjudicatory body may be called on to determine whether the level of protection (i.e. the length of the exclusivity period) is appropriate for the particular IPR in question, which entails an assessment as to its relative importance and societal value. The WTO adjudicatory bodies do not take it upon themselves to pass judgment over such questions. It would be unacceptable and at odds with the sovereignty of Member states. IP standards should be determined by mutual agreement of sovereign states rather than imposed on them by a judicial body.

To conclude, the outcome of this type of complaint is far from certain in the current framework. It is this uncertainty and the possibility of an absurd outcome that a multilateral agreement can help eliminate. It is submitted that in a hypothetical case where a data protection standard for biologics, such as the first version proposed above, was included in TRIPS, the above complaint would be unlikely to occur in the first place. WTO Members would have the requirements spelt out, which would result in a better understanding of the acceptable methods of implementation. That said, if a complaint did occur, an adjudicatory body would be well placed to determine whether a particular method of implementation of an accepted standard is appropriate.

IV. Potential conflicts arising from the proposed multilateral standard

The common thread through most of the discussed data protection provisions seems to be that clinical data relating to biologics should not be distinguished from that of chemical drugs, and at least the same protection should be afforded to them. The FTAs establish the common intention of the signatories that IP that exists in clinical data should not be denied protection on the basis that a pharmaceutical is manufactured one way or another.

If the multilateral standard for data protection for biologics is formulated in terms analogous to Art 39.3 of TRIPS, the policy space for domestic implementation remains relatively wide. The protection would be interpreted within the unfair competition framework with the obligation to protect data from unfair commercial use and/or disclosure, with no minimum exclusivity requirement. This wording allows WTO Members to implement the method and level of protection appropriate to their socio-economic needs.³⁰⁸

According to leading scholars, flexibility and aiming at an appropriate balance are important features of the IP obligations embedded in the multilateral framework.³⁰⁹ This is supported by Articles 7 and 8 of TRIPS, which contain important qualifications as to the objectives and principles of IP protection reflecting the intentions of the entire WTO membership.

³⁰⁷ Ibid.

³⁰⁸ TRIPS Art 1; see also Shaikh, *Access to medicine versus test data exclusivity: safeguarding flexibilities under international law* 91.

³⁰⁹ Grosse Ruse-Khan and others, 'Principles for intellectual property provisions in bilateral and regional agreements' 880.

Article 7 of TRIPS require that IP protection and the enforcement of IPRs should be “conducive to a social and economic welfare, and to a balance of rights and obligations.”³¹⁰ Article 8 of TRIPS allows Members to protect public health and to implement measures, where necessary, to prevent the practices which unreasonably restrain trade.³¹¹

The above obligations are part of the context within which Members may implement IP protection measures, and have direct effect on the level of protection that may be granted, as Art 1.1 of TRIPS provides that

Members may, but shall not be obliged to, implement in their law more extensive protection that is required by this Agreement, *provided that such protection does not contravene the provisions of this Agreement.*³¹²

Consequently, the international community agreed that IP protection should not hinder social and economic development or unreasonably restrain trade. Further, the Doha Declaration on TRIPS and public health acknowledges the importance of IP protection for the development of new medicines, but it also warns that TRIPS should “be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.”³¹³ Should the standard of protection of clinical data relating to biologics be accepted multilaterally and included in the WTO framework, in an analogous way to Art 39.3 of TRIPS, it is expected that the same principles should apply. Countries should be able to implement IP regimes that strikes the right cost-benefit balance. This is the purpose of the flexibilities and policy space created by the provision.

Controversially, as the concept and minimum standard of data protection for biologics are emerging from FTAs, the requirements under these provisions go further than establishing the underlying IPR. The typical FTA clause reduces the policy space by prescribing specific implementation methods resulting in a high level of IP protection. Insofar as there are conflicting opinions as to the appropriate methods of implementing Art 39.3 of TRIPS and whether data exclusivity is desirable or necessary, it would appear that the emergence of data protection for biologics brings along a similar tension between the implementation method and the underlying IP norm. The issue is further complicated by the fact that many FTAs do not properly anchor the created IP norm to existing standards, such as protection of undisclosed information or unfair competition. Further, different FTAs have different implementation requirements such as varying periods of exclusivity.

That said, while theoretically certain implementations of data protection can violate TRIPS, it is difficult to characterise a realistic instance of “more extensive protection” that may be found to “contravene” TRIPS.³¹⁴ On the other hand, the international harmonisation of IP protection entails the introduction of minimum requirements. Countries that do not provide protection for clinical data relating to biologics will be required to bring their domestic law in line with the new norm. It is submitted, however, that the example of India, discussed above, shows that there are ways of

³¹⁰ TRIPS art 7.

³¹¹ TRIPS arts 8.1 and 8.2.

³¹² TRIPS art 1:1, 2nd sentence (emphasis added).

³¹³ *Doha Declaration on the TRIPS Agreement and Public Health* paras 3-4.

³¹⁴ Grosse Ruse-Khan and Kur, 'Enough is Enough - The Notion of Binding Ceilings in International Intellectual Property Protection' 37-45.

implementing a TRIPS-like data protection standard that do not entail the granting exclusive rights that hinder trade in follow-on products.³¹⁵

V. Conclusions

It is a tribute to human ingenuity that medicines are made in an incredible variety of ways. Nevertheless, one may divide pharmaceuticals into two broad categories in terms of manufacture: chemical and biological medicines. Due to the high cost and financial risk associated with medical research and development, IP protection is a major concern for the innovative pharmaceutical industry. The protection of safety and efficacy data as a specific instance of the protection of undisclosed information is a unique IPR that applies to pharmaceutical products.³¹⁶ However, the only existing multilateral standard does not apply to all pharmaceuticals, only those that utilise an active ingredient manufactured by chemical means.³¹⁷ This formulation creates a division between chemical and biological medicines.

The role of biologics in current medical practice is significant. The manufacture and development of these products is research-intensive and complex. Consequently, biologics are very expensive compared to chemical drugs, accounting for a considerable portion of the overall value of trade in medicines. The paucity of an internationally recognised norm for the protection of clinical data associated with these medicines has undesirable consequences.

Countries with strong research-based pharma industry have been promoting data protection for biologics worldwide by including minimum requirements in bilateral and regional trade agreements. It is emerging from FTAs without an underlying mutual agreement, a phenomenon that potentially leads to confusion as to the basic principles of the IPR, and fundamental disagreements at the negotiating table. There have been two prominent examples of failed trade negotiations that, in my view, can be partially attributed to the lack of a principled, consensus-based approach.

First, the US withdrew from the TPP negotiations after the process stalled largely due to the majority of parties' steadfast opposition to the high IP standards put forward by the US. The second example is the amendment of the USMCA at the eleventh hour. After USTR managed to secure an unprecedented level of data protection for biologics, the US Congress refused to ratify the agreement. The Amendment Protocol introduced a small number of key amendments, one of which was the elimination of the ten-year data exclusivity period for biologics.

In both of the above examples, the excessive protection for biologics was eventually dialled back to the same level as for chemical drugs. It is submitted that these noteworthy events can be, at least partially, explained by the lack of a multilateral standard of data protection for biologics.

Notwithstanding, there are many examples of data protection provisions in successfully concluded FTAs. However, these provisions typically provide the IP standard along with the required method of implementation. This entanglement of two separate concepts is at the heart of the problem faced by those who try to properly characterise the underlying IP standard and its rationale. One must clearly separate the concepts of data protection and data exclusivity and define their relationship to IP law. I

³¹⁵ Cf TRIPS Preamble, recital 1.

³¹⁶ The other group of products that also enjoys such protection are agricultural chemicals.

³¹⁷ TRIPS, art 39.3.

have argued, for example, that data exclusivity is not an IPR but a regulatory tool that can be used as one method to enforce data protection.

In my view, data protection for biologics, like any other IPR, should be formulated by legislative means, or, on the international plane, by mutual agreement of the community. I argued that a multilateral standard would be desirable to create a more predictable legal environment and to enable appropriate enforcement by adjudicatory bodies.

I proposed two versions for the multilateral standard and submitted that, although it is highly unlikely that any such provision will be agreed on and introduced in the foreseeable future, the version modelled on Art 39.3 of TRIPS has the better chance to proceed. It has the advantage of using existing flexibilities, leaving considerable policy space for implementation.

Bibliography

— *Letter from Representative Jan Schakowsky et al. to Robert E. Lighthizer, U.S. Trade Representative* (Open letter, 11 July 2019)

— *New Zealand TPP Intellectual Property Chapter: Horizontal Issues/Overall Structure, General Provisions and Cooperation* (Leaked Document, 2010)

— *Status of Work in the Negotiating Group MTN.GNG/NG11/W/76* (Chairman's Report to the GNG, 23 July 1990)

Abutaleb Y and Dawsey J, 'White House races to come up with health-care wins for Trump's campaign' *Washington Post* (U.S. 1 August 2019) <https://www.washingtonpost.com/health/trump-to-unveil-drug-price-health-initiatives-in-walk-up-to-2020/2019/07/31/f4adc4de-af1a-11e9-8e77-03b30bc29f64_story.html> accessed 9 July 2020

Acquah D, 'Extending the limits of protection of pharmaceutical patents and data outside the EU - Is there a need to rebalance?' (2014) 45 *IIC International Review of Intellectual Property and Competition Law* 256

Adamini S and others, 'Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities' (2009) 34 *Journal of Health Politics, Policy and Law* 979

Biotechnology Innovation Organization (BIO), *A Follow-On Biologics Regime Without Strong Data Exclusivity Will Stifle The Development Of New Medicines* (White paper, 2007)

— *BIO Statement on the United States-Mexico-Canada Agreement* (4 October 2018)

— 'The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics' (*White Paper*, 2013) <https://www.bio.org/sites/default/files/legacy/bioorg/docs/files/TPP%20White%20Paper%20_2_.pdf> accessed 08 July 2020

Blakeney M, 'The Role of Intellectual Property Law in Regional Commercial Unions in Europe and Asia' (1998) 16 *Prometheus* 341

Buttigieg P, 'Affordable Medicine for All: A Plan to Slash Drug Prices and Boost Medical Innovation' (*Presidential Campaign Brochure*, 2019) <<https://peteforamerica.com/policies/affordable-medicine/>> accessed 1 February 2020

Carvalho NPd, 'Test Data Protection - The WIPO Perspective' (Symposium on the Evolution of the Regulatory Framework of Test Data - From the Property of the Intellect to the Intellect of Property)

Carvalho NPd, *The TRIPS Regime of Antitrust and Undisclosed Information* (Kluwer Law International 2008)

— *The TRIPS regime of patent rights* (Kluwer Law International 2002)

Chalasani R, Donohue JM and Gellad WF, 'Prescription 2020: Democratic Candidates And Drug Pricing' (*Heath Affairs Blog*, 2019) <<https://www.healthaffairs.org/doi/10.1377/hblog20190826.689286/full/>> accessed 9 July 2020

Cook T, 'Data protection and market exclusivities for pharmaceuticals in the EU' (2014) 16 *Pharmaceuticals Policy and Law* 19

Cooper Dreyfuss R, 'Harmonization: Top Down, Bottom Up - and Now Sideways?' in Kingsbury B (ed), *Megaregulation contested: global economic ordering after TPP* (Oxford University Press 2019)

Correa CM, 'Flexibilities provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights' (2018) 96 *World Health Organization Bulletin of the World Health Organization* 148

— 'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements' in Roffe P, Tansey G and Vivas-Eugui D (eds), *Negotiating Health Intellectual Property and Access to Medicines* (Routledge 2012)

— *Research handbook on the protection of intellectual property under WTO rules* (Edward Elgar 2010)

— *Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement* (Oxford University Press 2007)

Deloitte, 'Avoiding no man's land: potential unintended consequences of follow-on biologics' (*White Paper*, 2009) <http://www.pharmamanufacturing.com/Media/1001/Deloitte_Biosimilars.pdf> accessed 10 April 2019

Diependaele L, Cockbain J and Sterckx S, 'Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity' (2017) 17 *Developing World Bioethics* 11

— 'Similar or the Same? Why Biosimilars are not the Solution' (2018) 46 *The Journal of Law, Medicine & Ethics* 776

Drahoš P, 'Global property rights in information: the story of TRIPS at the GATT' (1995) 13 *Prometheus* 6

European Commission, 'Commission welcomes green light to start trade negotiations with Australia and New Zealand' (*EC Official News Archive*, 22 May 2018) <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1843>> accessed 13 July 2020

— 'EU-Australia Trade Agreement negotiations' (*EC Official News Archive*, 21 June 2018) <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1865>> accessed 22 July 2020

— 'EU-New Zealand Trade Agreement negotiations' (*EC Official News Archive*, 21 June 2018) <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1867>> accessed 22 July 2020

— *Individual reports and info sheets on implementation of EU Free Trade Agreements* (Commission Staff Working Document, 14 October 2019)

— 'New EU-Mexico agreement: The Agreement in Principle and its texts' (*EC Official News Archive*, 28 April 2018) <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1833>> accessed 22 July 2020

— *Report on the protection and enforcement of intellectual property rights in third countries* (Commission Staff Working Document, 8 January 2020)

European Medicines Agency, 'Biosimilar medicines: Overview' (*EMA Official website*, 2019) <<https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview#biosimilar-development-and-approval-in-the-eu-section>> accessed 12 July 2020

— *Guideline on similar biological medicinal products CHMP/437/04 Rev 1* (23 October 2014)

Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Completion* (Report, 2009)

Feldman R and Frondorf E, 'Drug Wars: A New Generation of Generic Pharmaceutical Delay' (2016) 53 *Harvard Journal on Legislation* 499

Frieden J, 'Trump: U.S. Will Withdraw from TPP' (*Medpage Today*, 23 January 2017) <<https://www.medpagetoday.com/publichealthpolicy/healthpolicy/62691>> accessed 16 July 2020

Gervais D, *International Intellectual Property's Institutional Problem* (Kluwer Copyright Blog 2018)

— *The TRIPS Agreement: drafting history and analysis* (4th edn, Sweet & Maxwell 2012)

Gleeson D and others, 'Financial costs associated with monopolies on biologic medicines in Australia' (2019) 43 *Australian Health Review* 36

Grabowski H, 'Data exclusivity for new biological entities' (2007) 8 *Duke University Department of Economics Working Paper*

Grosse Ruse-Khan H and Kur A, 'Enough is Enough - The Notion of Binding Ceilings in International Intellectual Property Protection' (8 December 2008) *Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No 09-01 1*

— and others, 'Principles for intellectual property provisions in bilateral and regional agreements' (2013) 44 *IIC-International Review of Intellectual Property and Competition Law* 878

— 'Principles for intellectual property provisions in Bilateral and Regional Agreements' (2014) 36 *European Intellectual Property Review* 207

— 'Protecting Intellectual Property under BITs, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?' (2011) *Evolution in investment treaty law and arbitration* 485

Hegedus-Gaspar M, 'Data Exclusivity for Biological Pharmaceuticals: Is New Zealand in Breach of World Trade Organization Law?' (2016) 50 *Journal of World Trade* 909

Ho C, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (2011)

Hollis A, 'Me-too drugs: is there a problem?' (*WHO Commission on Intellectual Property Rights, Innovation and Public Health*, 2004) <https://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs_Hollis1.pdf> accessed 08 July 2020

House Committee on Ways & Means, *Improvements to the USMCA* (Fact Sheet, 2019)

IFPMA, 'Data Exclusivity: Encouraging Development of New Medicines' (*International Federation of Pharmaceutical Manufacturers & Associations*, July 2011) <https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_2011_Data_Exclusivity__En_Web.pdf> accessed 18 July 2020

IQVIA Institute, 'Global pharma spending will hit \$1.5 trillion in 2023' (*Pharmaceutical Commerce*, 2019) <<https://pharmaceuticalcommerce.com/business-and-finance/global-pharma-spending-will-hit-1-5-trillion-in-2023-says-iqvia/>> accessed 08 May 2019

Kantardjieff A and Zhou W, 'Mammalian cell cultures for biologics manufacturing' (2014) 139 *Advances in biochemical engineering/biotechnology* 1

Knightley P, *Suffer the Children: the Story of Thalidomide* (Carlton Books Limited 1979)

Leonard K, 'Budget Breakers' (*US News*, 24 September 2015) <<https://www.usnews.com/news/the-report/articles/2015/09/24/expensive-drugs-a-drag-on-consumers-and-government>> accessed 18 July 2020

— 'Can the Government Already Control Drug Prices?' (*US News*, 11 January 2016) <<https://www.usnews.com/news/articles/2016/01/11/congressional-democrats-urge-nih-to-act-on-drug-prices>> accessed 18 July 2020

Lester SN, Mercurio B and Davies A, *World trade law: text, materials, and commentary* (Third edn, Hart Publishing, an imprint of Bloomsbury Publishing Plc 2018)

Levine ME and Forrence JL, 'Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis' (1990) 6 *Journal of Law, Economics, & Organization* 167

Ministry of Foreign Affairs and Trade, *TPP Overview Fact Sheet* (New Zealand-specific fact sheets on the content of TPP, 2015)

Mitchell CW, Roscett JH and Cyr S, 'Dead Zone: Are Your Biological Products Ready For FDA's Regulatory Transition?' *American Pharmaceutical Review* <<https://www.americanpharmaceuticalreview.com/Featured-Articles/337397-Dead-Zone-Are-Your-Biological-Products-Ready-for-FDA-s-Regulatory-Transition/>> accessed 07 May 2019

Moberg K, 'Private industry's impact on U.S. trade law and international intellectual property law: a study of post-TRIPS U.S. Bilateral Agreements and the capture of the USTR' (2014) 96 *Journal of the Patent and Trademark Office Society* 228

Morgan MR, 'Regulation of innovation under follow-on biologics legislation: FDA exclusivity as an efficient incentive mechanism' (2010) 95 *Columbia Sci Technol L Rev* XI

Narsana B, Chattopadhyaya S and Mahajan Y, 'Clinical Trials and Data Exclusivity: In Search of a Fine Balance' (2017) March 2017 *Pharma Bio World* 10

Office of the General Counsel, US Trade Representative, 'Special 301 Report on Intellectual Property Protection and Review of Notorious Markets for Counterfeiting and Piracy' (*USTR Official website*, 2020) <https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf> accessed 19 July 2020

— *The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3* (Unattributed paper for submission in bilateral discussions with Australia, 1995)

Office of the United States Trade Representative, 'Issue Areas: Intellectual Property' (*USTR Official website*, 2018) <<https://ustr.gov/issue-areas/intellectual-property>> accessed 12 July 2020

— 'Statement on USMCA and Drug Prices' (*USTR Official website*, 2019) <<https://ustr.gov/about-us/policy-offices/press-office/press-releases/2019/march/ustr-statement-usmca-and-drug-prices>> accessed 12 July 2020

Okomura Y, 'Drug Re-Examination/Data Exclusivity in Japan and Neighboring Countries' (AIPPI Forum & ExCo Workshop Pharma IV, Helsinki)

Otto R, Santagostino A and Schrader U, 'Rapid growth in biopharma: Challenges and opportunities' McKinsey Co <<http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/rapid-growth-in-biopharma>> accessed 07 May 2019

Parmuk J, 'House Democrats and the White House have a deal to move forward with USMCA trade agreement' (CNBC, 11 December 2019) <<https://www.cnbc.com/2019/12/10/house-democrats-and-trump-administration-reach-usmca-trade-deal.html>> accessed 18 July 2020

Reichman JH, 'Legal Hybrids between the Patent and Copyright Paradigms' (1994) 94 Columbia Law Review 2432

— 'The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?' in Roffe P, Tansey G and Vivas-Eugui D (eds), *Negotiating Health Intellectual Property and Access to Medicines* (Routledge 2012)

— 'Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective' UNCTAD-ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning <https://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf> accessed 29 April 2019

Riffel C, *Mega-regionals* (Max Planck Encyclopedias of International Law, 2016)

— *Protection against unfair competition in the WTO TRIPS Agreement: the scope and prospects of Article 10bis of the Paris Convention for the Protection of Industrial Property*, vol 2 (Brill Nijhoff 2016)

Roberts A and St John T, 'UNCITRAL and ISDS Reform: Plausible Folk Theories' (*International Economic Law and Policy Blog*, 13 February 2020) <<https://ielp.worldtradelaw.net/2020/02/uncitral-and-isds-reform-plausible-folk-theories.html>> accessed 17 July 2020

Sanjuan Rius J, Love J and Weissman R, 'The Protection of Pharmaceutical Test Data: A Policy Proposal' (2006) <<http://keionline.org/print/book/export/html/438>> accessed 2019 November 11

— 'U.S and E.U Protection of Pharmaceutical Test Data' CPTech Discussion Paper - No 1 <<http://cptech.org/publications/CPTechDPNo1TestData.pdf>> accessed 08 May 2019

Sanzo MA, 'The Promise and Problem of Biologics' (2017) 34 HTLJ 78

Schiestl M, Zabransky M and Sörgel F, 'Ten years of biosimilars in Europe: development and evolution of the regulatory pathways' (2017) 11 Drug Des Devel Ther 1509

Sell SK, 'TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP' (2011) 18(2) J Intell Prop L 447

— 'TRIPS-plus free trade agreements and access to medicines' (2007) 28 Liverpool law review 41

Shaikh OH, *Access to medicine versus test data exclusivity: safeguarding flexibilities under international law* (Springer 2016)

Spina Ali G, 'The 13th Round: Article 39(3) TRIPS and the struggle over "Unfair Commercial Use"' (2018) 21 The Journal of World Intellectual Property 201

Stepniewska B, 'Test Data Protection - generic and biosimilar industry perspective' (WIPO Symposium)

Stevenson A, *Oxford dictionary of English* (Oxford University Press 2010)

Sukduang S and Sullivan TJ, 'The Patent Dance' European Biopharmaceutical Review <<https://www.finnegan.com/en/insights/the-patent-dance-article.html>> accessed 28 May 2019

Tang L, 'Data protection provisions in CETA' (*Generics and Biosimilars Initiative*, 2014) <<http://www.gabionline.net/Generics/Research/Data-protection-provisions-in-CETA>> accessed 08 July 2020

The Pharma Letter, 'Why IP protections are important for biologic medicines' (*Biotechnology news*, 19 July 2019) <<https://www.thepharmaletter.com/article/why-ip-protections-are-important-for-biologic-medicines>> accessed 1 February 2020

Trump DJ, 'Presidential Memorandum Regarding Withdrawal of the United States from the Trans-Pacific Partnership Negotiations and Agreement' (*Whitehouse Official Website*, 23 January 2017) <<https://www.whitehouse.gov/presidential-actions/presidential-memorandum-regarding-withdrawal-united-states-trans-pacific-partnership-negotiations-agreement/>> accessed 16 July 2020

U.S. Department of Health and Human Services, *Examination of Clinical Trial Costs and Barriers for Drug Development* (25 July 2014)

U.S. Food & Drug Administration (FDA), 'Biosimilar Development, Review, and Approval' (*FDA Official website*, 2017) <<https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval>> accessed 12 July 2020

— *Estimating Cost Savings From Generic Drug Approvals In 2017* (Report, 2017)

VC NewsNetwork, 'Global Biologics and Biosimilars Market 2019 Overview, Size, Share, Trend, Insights, Research, Review, Regional Analysis, Forecast Growth Report 2025' (*Reuters*, 2019) <<https://www.reuters.com/brandfeatures/venture-capital/article?id=77743>> accessed 8 May 2019

WIPO, 'What is Intellectual Property?' (*WIPO Official website*, 2019) <<https://www.wipo.int/about-ip/en/>> accessed 15th October 2019

Yu PK, 'Data Exclusivities and the Limits to TRIPS Harmonization' (2019) 45 Florida State University Law Review 18

— 'The non-multilateral approach to international intellectual property normsetting' (*Research Handbook on International Intellectual Property Law*, Daniel J. Gervais, ed., Edward Elgar Publishing, 2014) <<https://ssrn.com/abstract=2325766>> accessed 15 July 2020